March 20, 2018 - P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 20, 2018 12:59 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 4 P.M.

(Pages 780 through 899)

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I N D E X

TESTIMONY

E X H I B I T S

E X H I B I T S (Continued)

Number		Ident	Rec'd
2057			897
2244			897
2321			897
3781	Medical Article - 2009 BPV-15-0100106166, Binkert, et al., Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study, J. Vasc. Interv. Radiol. 2009; 20:1449-1453, Kinney Kalva Roberts, Hurst, Eisenberg, Kessler	864	
4282	Demonstrative: Exemplar G2 Filter	797	800
4359	Demonstrative: 2014_6_26 CT Axial Leg interaction with Right Psoas	811	811
4360	Demonstrative: 2014_6_24 CT Axial Arm in Heart	807	808
4370	Demonstrative: 2007_6_21 Scout view CT Pelvis Filter at L2	801	802
4385	Scout view of abdomen from CT done 6-24-2014	809	810
4386	axial image from a CT of the heart from 7-24-2014	813	813
4388	Economic table created by Matthew Sims, demonstrative exhibit	890	

RECESSES

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(Recess at 2:31; resumed at 2:44.)	843	19

P R O C E E D I N G S

(Jury enters at 12:59.)

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you. Please be seated.

All right. Mr. O'Connor? 12:59:56

MR. O'CONNOR: Yes, Your Honor. The next witness will be --

THE COURT: We couldn't hear that.

MR. O'CONNOR: -- Darren Hurst.

COURTROOM DEPUTY: Sir, if you'll please come forward and raise your right hand. 01:00:08

(DARREN R. HURST, M.D., a witness herein, was duly sworn or affirmed.)

COURTROOM DEPUTY: Could you spell your last name for the record, please. 01:00:22

THE WITNESS: H-U-R-S-T.

MR. O'CONNOR: May I proceed?

THE COURT: You may.

DIRECT EXAMINATION

BY MR. O'CONNOR: 01:01:20

Q. Would you please state your name.

A. My name is Darren Hurst.

Q. And what do you do for a living?

A. I'm an avascular and interventional radiologist.

Q. And Dr. Hurst, could you please tell the members of the 01:01:31

jury where you practice medicine at? 01:01:34
A. I practice in the Cincinnati, Ohio, area at St. Elizabeth Hospital. It's a tertiary care medical center.
Q. And when you say that you are an interventional radiologist, tell the members of the jury what that is, what 01:01:48
you do.
A. So interventional radiologists perform minimally invasive procedures using image guidance to treat various diseases using low-risk procedures that have pretty much replaced a lot of different types of surgeries. Our main focus is vascular 01:02:15
disease.
Q. In your practice, do you or have you in the past used IVC filters?
A. Yes.
Q. And have you implanted IVC filters? 01:02:26
A. Yes.
Q. And does that include Bard IVC filters?
A. Yes.
Q. And in your practice do you remove or retrieve IVC filters? 01:02:37
A. Yes.
Q. Dr. Hurst, can you explain what your role here is, what you were requested to do?
A. To evaluate the Bard G2 filter in Sherr-Una Booker and determine the modes of failure of the device and also to 01:02:50

determine whether the implanting physicians for the G2 device were properly warned or adequately warned of the potential risks and complications or dangers of the device. 01:02:53

Q. And did you also review medical records and medical imaging? 01:03:11

A. Yes.

Q. And are you going to explain the imaging as it relates to Ms. Booker?

A. Yes.

Q. So in those three areas, can you tell us, what are your opinions? 01:03:19

A. My opinion is that the Bard G2 filter in Ms. Booker failed. It had multiple modes of failure including excessive tilt, perforation of the inferior vena cava, perforation of adjacent organs to the inferior vena cava, fracture, and migration and also embolization or a fragment breaking off the filter and actually traveling through the vascular system to Ms. Booker's heart. 01:03:39

Q. Thank you.

Now, you told us that you are a doctor who specializes in vascular and interventional radiology and you practice in the Ohio, Kentucky, and Indiana area; is that right? 01:04:06

A. Correct.

Q. Would you tell us briefly about your educational 01:04:20

background? What training you received to become medical doctor? 01:04:23

A. So I went to Miami University in Oxford, Ohio, for my undergrad and then I went to the University of Cincinnati College of Medicine. Then I went to the University of Michigan for my residency in radiology and then I did a fellowship in vascular interventional radiology also at the University of Michigan. 01:04:31

Q. And when did you start practicing?

A. 2001. 01:04:50

Q. What positions do you currently hold in your field, your area of interventional radiology?

A. I'm currently the Director of the Department of Vascular and Interventional Radiology and we cover eight cath labs in our hospital system. I'm also the Chairman of the Product Committee which I have been for the last ten years, and our job is to review the thousands of products that we use every day, the medical devices in our system, and determine whether they are appropriate for use based on their safety, on the economy of the device and on its effectiveness. 01:05:04 01:05:26

Q. Have you in your practice used Bard filters in the past?

A. Yes, I've used the Simon Nitinol filter, the Recovery filter, the G2 Filter, and the Meridian filter.

Q. Do you still use those?

A. I do not. 01:05:45

Q. Why? 01:05:46

A. They are all off the market currently.

Q. And Dr. Hurst, in arriving at your opinions in this case, could you just -- I see you brought a filter. Could you, first of all, just explain to the jury the implant process of an IVC 01:06:05 filter using your model up there?

A. Sure. So an inferior vena cava filter is a wire mesh device that looks basically like a teepee. These are two different types of filters here and these devices are implanted in the inferior vena cava. This is a model of the inferior 01:06:30 vena cava which is the largest vein in the body. And it carries the blood flow back from the legs to the heart.

The reason that these devices are placed is when a patient has DVT or clot in their leg vein, they are at risk for that clot breaking off and going through the inferior vena cava 01:06:50 into the heart and lungs where it can cause significant complications including sudden death. That is called pulmonary embolism.

So in order to keep a DVT or a deep vein thrombosis from going to the heart or lungs, there are two options. One 01:07:09 is to places the patient on blood-thinning medication so that the clot stabilizes and doesn't break free and go to the heart and lungs. If the patient cannot be placed on blood-thinning medication, the alternative treatment is to place a filter and these filters are collapsed in a tube or catheter such that the 01:07:30

legs are all collapsed upon themselves and then it's delivered through the vessels, through the blood vessels to the appropriate location under x-ray guidance and then deployed just like that. And the idea is that as the clot goes up through the IVC, it's captured by this device and the body can either break it down or sometimes it actually just stays in the filter. 01:07:38 01:07:52

Q. Now, in your work in the part of the country where you practice with your group, you told us that you were using Bard filters at one time. You've implanted filters and you have removed filters? 01:08:11

A. Yes.

Q. Are you doing as many now in recent years as you were?

A. No. We significantly decreased the number of filters that we're placing. 01:08:26

Q. When you were preparing to come here and talk to this jury, can you tell us what you did to prepare your opinions? You prepared a report; correct?

A. Sure. Yes.

Q. And you arrived at opinions that you summarized for us? 01:08:36

A. Correct.

Q. What did you do to come to that point?

A. So in preparation for my report and in getting my opinions, I reviewed Ms. Booker's medical records, all of her imaging, the instructions for use for the G2, the Recovery and 01:08:52

multiple other filters, the relevant medical literature, I did a systematic review of the literature including a Medline search, a search through the vascular interventional radiology journals and pulled all of those articles and evaluated them and I evaluated the medical -- I'm sorry, the expert witness reports and depositions for the case. 01:08:58 01:09:17

Q. Now, in your practice when you were using Bard filters, did you receive marketing materials and brochures?

A. Yes.

Q. And are you familiar with those documents? 01:09:37

A. Yes. We see those documents all the time as part of the Product Committee.

MR. O'CONNOR: I would like to display Exhibit 2045, please.

Greg, can you just page through it real quick for Dr. Hurst. 01:10:00

BY MR. O'CONNOR:

Q. All right. Dr. Hurst, can you identify what we're looking at in Exhibit 2045?

A. Yes. 01:10:17

Q. What is it?

A. This is the brochure that is given to the physicians by Bard to basically market the device.

Q. And this is something -- is this a document that you received when you were using -- is this consistent with the 01:10:31

type of information you received when you were using the Bard filters? 01:10:36

A. Yes.

MR. O'CONNOR: At this time, Your Honor, I would move into admission Exhibit 2045. 01:10:43

MR. NORTH: Objection, Your Honor. 402. No evidence that the implanter saw this.

THE COURT: Overruled. 2045 is admitted.

(Exhibit Number 2045 was admitted into evidence.)

MR. O'CONNOR: May I publish this to the jury, Your Honor? 01:10:56

THE COURT: You may.

BY MR. O'CONNOR:

Q. Dr. Hurst, you've reviewed the medical records and imaging studies for Sheri Booker; correct? 01:11:07

A. Yes.

Q. Do you have an understanding when she received her Bard G2 filter?

A. Yes.

Q. When? 01:11:14

A. 2007.

Q. And at that time, was that Bard G2 filter a permanent filter?

A. The Bard G2 filter was marketed as a permanent device, yes. 01:11:25

Q. Now, as we go through -- 01:11:26

MR. O'CONNOR: Greg, could you have the next page of Exhibit 2045?

BY MR. O'CONNOR:

Q. Dr. Hurst, is this how the filter was marketed to you and your group and the medical community when the G2 was cleared for market? 01:11:42

A. This is how it was marketed to my group, yes.

Q. And was G2 -- was it represented as a filter that had increased migration resistance? 01:11:58

A. Yes.

Q. Was it represented as a filter that had improved centering?

A. Yes.

Q. And was it represented as a filter that had enhanced fracture resistance? 01:12:07

A. Yes.

Q. And is this among the information that physicians like you would rely on from a company like Bard?

A. Yes. 01:12:19

Q. And is this the type of information that you expect that if Bard would make those statements, there was testing and studies to support that?

A. Absolutely.

Q. All right. So when you look at increased migration 01:12:29

resistance, did that prove out to be consistent with the experience that you and other interventional radiologists had? 01:12:31

A. We did not.

Q. What did you find?

A. We found that this had issues with caudal migration, which means that the device would actually move within the inferior vena cava sometimes up to two or three centimeters. And this experience was the same as some of our colleagues and then also it was borne out in the relevant literature of that time and so it was also borne out in the -- or shown to be true in the MAUDE database which is the database where complaints are filed to the FDA. 01:12:45 01:13:07

Q. Dr. Hurst, according to Exhibit 2045, Bard represented the G2 permanent filter as having improved centering. What did that mean to interventional radiologists like yourself back at the time that Bard was representing this filter to have that quality? 01:13:30

A. Well, centering is related to tilt so basically what they are saying is instead of improved centering, they are saying it's not going to tilt as much as some conical devices do. The predicate device for this filter or basically one of the filters this filter was designed after is the Greenfield filter which has been around for about 20 or 30 years and this device, one of its weaknesses was that sometimes it would sit in the inferior vena cava like this (Indicating) so it would be tilted 01:13:47 01:14:12

to one side. I don't know if you can see it. But. So -- when the filter is tilted to one side, there are studies that show it decreases IVC efficacy meaning that it won't block as many clots from going to the lungs because when it's on its side like that, there are wider spaces between the legs that allow clots to pass through. 01:14:15 01:14:38

The other issue with tilting is that when the tip of the filter interacts with the wall of the cava, the top of the filter, the wall of the cava will create a reaction around the top of the filter which can, number one, cause narrowing of the cava and, number two, make it difficult to retrieve if you are going to attempt to retrieve the filter. 01:15:01

Q. When Bard represented back at the time that the G2 came out as a permanent filter that it had improved centering, did you and the physicians in your area rely on that representation? 01:15:20

MR. NORTH: Objection, 402.

THE WITNESS: Yes.

THE COURT: Sustained.

BY MR. O'CONNOR: 01:15:31

Q. We're going to talk about physician expectations but do you have an expectation, Dr. Hurst, that when a company like Bard makes representations about its devices such as filters that they are accurate statements and based upon testing and studies? 01:15:49

A. Yes. 01:15:50
Q. And in your experience with the G2 filter, did it prove to you to meet what Bard represented, that it had improved centering?
A. No. 01:16:00
MR. NORTH: Objection, 402. No such claim. Misrepresentation. There's no claim of that here.
THE COURT: I'm not understanding what you mean by no claim.
MR. NORTH: Objection. Rule 402 because there is no misrepresentation claim in the case. 01:16:11
THE COURT: Would you reask the question, please, Mr. O'Connor?
MR. O'CONNOR: Sure.
BY MR. O'CONNOR: 01:16:21
Q. Did you expect as a physician, have a reasonable expectation that if Bard made a statement to physicians like you that the G2 permanent device had improved centering, that that was based upon Bard's work, studies, and testing?
A. Yes. 01:16:38
MR. NORTH: Same objection.
THE COURT: Overruled.
BY MR. O'CONNOR:
Q. And in reality, when you were actually out there using the G2 filter as a permanent device, did it approve to have that 01:16:44

feature? 01:16:50
A. No.
Q. What did you see?
A. Well, the studies that were done on the filter, the literature showed that it had an increased risk of tilting. In 01:16:56
addition, my personal experience with the filter was that it would tilt more often than other devices except for perhaps the Greenfield filter.
Q. And Dr. Hurst, if you look at the G2 permanent placement brochure that we're looking at, Exhibit 2045, Bard represented 01:17:21
back at the time that the G2 permanent filter was marketed that it had enhanced fracture resistance.
Now, as a physician, an interventional radiologist in the community, did you reasonably expect that to make that statement, Bard did the appropriate testing and conducted the 01:17:44
appropriate studies?
A. Yes.
Q. And what did you find as the G2 was being used in your patients? Was that accurate?
A. I personally did not have any fracture complications but 01:17:59
there were reports and there's literature that supports that the incidents of fracture for this device was higher than what was seen with other devices.
Q. And "this device" being the G2; is that correct?
A. Yes. 01:18:14

Q. Thank you. 01:18:15

MR. O'CONNOR: Excuse me, Your Honor. May I just step back to get another exhibit?

THE COURT: Yes.

MR. O'CONNOR: May I approach the witness, Your Honor? 01:18:31

THE COURT: Yes.

BY MR. O'CONNOR:

Q. I'm going to show you Exhibit 4282.

MR. NORTH: Your Honor, I'm very sorry to interrupt. 01:18:41
I would move to strike his last answer talking about complication rates because under the Court's *Daubert* order, he was precluded from discussing things of that nature on page five.

THE COURT: Why don't we address that from a sidebar 01:18:54
while you have somebody figure out if that's the right exhibit.

MR. O'CONNOR: I'm sorry?

THE COURT: Do you need no check on that exhibit?

MR. O'CONNOR: I don't believe it's in evidence. I was going to ask him to identify it. 01:19:06

THE COURT: Okay. Before you do that, come over here.

If you want to stand up, ladies and gentlemen.

(At sidebar 1:19.)

THE COURT: So I see on page six, Mr. O'Connor, that 01:19:36

this is line 17 that this doctor cannot present an expert opinion that Bard IVC filters did, in fact, have higher complication rates and unacceptable risks of caudal migration. 01:19:39

You just asked him that question, didn't you?

MR. O'CONNOR: No. 01:20:01

MR. NORTH: He offered the answer. He didn't ask the question.

MR. O'CONNOR: I asked him the question about just based upon that representation, if he relied on studies and what did he see out there when he was there. And he said he 01:20:09 saw that there was fracture. He didn't say anything --

THE COURT: Well, he went on to say the literature, the MAUDE data I think. I've got it all. Hold on. He said that he did not have fracture complications but the literature suggests fracture rates higher than other devices. 01:20:37

And you're asking me to strike that answer?

MR. NORTH: Right. Exactly.

THE COURT: I think I specifically ruled that he could not express opinions about complication rates based on what was in the literature. 01:20:56

MR. O'CONNOR: And I understand that ruling, Your Honor. That was not the intent of the question. The question was just to compare what was represented and what he saw.

THE COURT: Okay.

MR. O'CONNOR: So I certainly wasn't trying to -- 01:21:09

MR. NORTH: No. I'm not suggesting that. 01:21:11

THE COURT: So you want me to tell the jury to disregard the answer he gave about what the literature suggested on higher fracture rates?

MR. NORTH: Yes, Your Honor. 01:21:20

THE COURT: Do you have any objection to that?

MR. O'CONNOR: I think that's fair.

THE COURT: Okay.

(End of sidebar discussion.)

THE COURT: Thank you, ladies and gentlemen. I am going to instruct the jury to disregard the last answer that was given suggesting that the literature showed higher fracture rates for the G2. 01:21:30

Please disregard that testimony.

You can take that up to the witness. 01:21:47

BY MR. O'CONNOR:

Q. Dr. Hurst, I'm showing you Exhibit 4282 and I would like -- I want you to tell us if you're familiar with that package.

A. This is the package for the G2 filter. This is how it's delivered to the department. 01:22:00

Q. All right. Well, is that the type of packaging that you receive from Bard when you were using the filter?

A. Yes.

\\\

MR. O'CONNOR: Your Honor, I don't have the number written down but I would move to -- 01:22:14

THE COURT: 4282?

MR. O'CONNOR: Yes. I would move for its admission.

MR. NORTH: No objection, Your Honor. 01:22:21

THE COURT: 4282 is admitted.

(Exhibit Number 4282 was admitted into evidence.)

BY MR. O'CONNOR:

Q. And, Dr. Hurst, if you could show that packaging to the jury, what does it say? 01:22:28

A. It says: Recovery, timeless performance and then up here at the Recovery G2 filter system, femoral.

Q. And was that your understanding that the G2 was based upon the original Recovery filter?

A. Yes. 01:22:45

Q. All right. Thank you. You may set that down.

Now, Dr. Hurst, before we get into your opinions about reasonable expectations of a medical device company and your other opinions you talked about, let's talk about your opinions regarding Sheri Booker; okay? You reviewed medical 01:23:17 records and imaging studies; is that right?

A. Yes.

Q. And can you tell us what you found in reviewing that? What did the G2 filter do after it was implanted in Ms. Booker?

MR. NORTH: Objection, Your Honor. Cumulative of 01:23:36

Dr. Murphy's testimony. 01:23:38

THE COURT: I think that ground was covered with Dr. Muehrcke.

MR. O'CONNOR: Your Honor, I'm going to ask him to look at specific imaging and explain to the jury what he sees. 01:23:46

THE COURT: Then let's go to that imaging. I think the general questions were covered.

MR. O'CONNOR: Greg, could you put up Exhibit 4370, please.

BY MR. O'CONNOR: 01:24:24

Q. Dr. Muehrcke, can you identify Exhibit 4370?

A. I'm Dr. Hurst. Yes, I can.

Q. Pardon me?

MR. LOPEZ: You called him Dr. Muehrcke.

MR. O'CONNOR: Oh. I'm sorry. Dr. Hurst, I apologize. We were just talking about Dr. Muehrcke. Actually, I have his name written down here. 01:24:38

BY MR. O'CONNOR:

Q. Dr. Hurst, I apologize.

A. This is the scout view or the localizer view for a CT scan that was done on the day of the implantation of the filter on Ms. Booker. So this is the equivalent of an abdominal x-ray but it's done with a CT scan to help the CT tech decide from where to where to scan basically. 01:24:46

Q. And what is the date of this imaging study, Dr. Hurst? 01:25:10

A. This 6-21-07. 01:25:13

MR. O'CONNOR: At this time, I would move for its admission, Your Honor.

THE COURT: Any objection?

MR. NORTH: I'm sorry. No objection, Your Honor. 01:25:24

THE COURT: All right. 4370 is admitted.

(Exhibit Number 4370 was admitted into evidence.)

MR. O'CONNOR: And may we publish to the jury, Your Honor?

THE COURT: Yes. 01:25:31

BY MR. O'CONNOR:

Q. Dr. Hurst, I think on your screen there's a way that you can outline things.

THE COURT: You just touch the screen.

BY MR. O'CONNOR: 01:25:47

Q. First of all, it was Dr. D'Ayala that did the implant?

A. Yes.

Q. And can you describe to the jury the position of the filter after implant, please?

A. Yes. So the inferior vena cava obviously you can't see on 01:25:57 this study here, but from the location of this filter, it is likely centered within the inferior vena cava. The IVC would run basically like this.

And the tip of the filter is at the what we call the inferior pedicle or the inferior aspect of the pedicle of the 01:26:22

second lumbar vertebral body or L2. So this is an appropriately positioned filter. 01:26:27

Q. And it's appropriately positioned because what is it about the filter that you can look at and say it's positioned correctly? 01:26:40

A. Well, we know that the renal veins are just a little bit above where the L2 vertebral body is and we would like to have that filter just a little bit below the renal veins which would come off like that (Indicating). That's the rest of the inferior vena cava, so we would like to have the filter below 01:26:59 the level of the renal veins and we don't want it at the renal vein because we don't want to it obstruct the renal vein flow. And the renal veins are basically the veins that come from the kidneys, flow like that.

Q. And by the way, there is an arrow and there's L2. Did you 01:27:13 add that to this imaging study?

A. Yes, I did.

Q. And what was your purpose for doing so?

A. Just to demonstrate to the jury where the second lumbar vertebral body was and the arrow is basically to demonstrate 01:27:26 where the tip or the top of the filter is.

Q. And do you have an opinion to a reasonable degree of certainty whether the G2 filter was appropriately positioned and implanted in Sheri Booker when it was done so by Dr. D'Ayala? 01:27:45

A. Based on this imaging, yes. 01:27:46
Q. Thank you. Oh, by the way, Dr. Hurst, before we move on, we've heard testimony about different types of radiologists. You are an interventional vascular radiologist. What is a diagnostic radiologist? 01:28:00
A. So a diagnostic radiologist does four years of training in learning how to read diagnostic medical images: CT scans, MRIs, ultrasound, x-rays. Interventional radiology is additional training beyond your diagnostic radiology residency and usually during your final year of diagnostic radiology, you 01:28:24
do almost a whole year of interventional radiology as well. So it's basically two years of training in just image-guided procedures. So just doing angioplasties and stents and chest boards and vascular access, things like that. So it's an additional year of training in just interventional radiology. 01:28:47
Q. So you're actually doing procedures to implant devices or do radiographic studies that involve going into a patient; is that correct?
A. Right.
MR. NORTH: Objection. Leading. 01:29:04
THE COURT: Overruled.
MR. O'CONNOR: Thank you.
BY MR. O'CONNOR:
Q. Dr. Hurst, when you look at the filter as it's positioned on Exhibit 4370, this is the date that it was implanted, can 01:29:13

you just circle for the jury so they will know if they read or look at this imaging where they can find the date? 01:29:21

A. (Witness complies).

Q. And is that the date, as you understand it, of the implant or around that time? 01:29:37

A. Yes.

Q. Now, you told us it was appropriately implanted and you told us that this G2 was marketed as a permanent device?

A. Correct.

Q. In terms of reasonable expectations, what were the reasonable expectations of interventional radiologists back in 2007 as to what it meant to have a permanent filter for a patient? 01:29:50

A. Well, the expectations of an interventional radiologist are the same as any consumer or patient. You know, you expect the device to be safe for its intended use, at least as safe as reasonably possible. You expect the device to be effective so it should provide some sort of benefit to the patient. Otherwise, you're not going to put the device in the patient. 01:30:12

And you expect the device to be at least as effective as the prior iterations of the device or the alternatives to the device. Otherwise, you're just not going to use it. 01:30:32

Q. Now, in terms of this G2 and marketed as a permanent device, was there an expectation as to how the filter would remain and what position it would remain in? 01:30:53

A. Well, the experience with permanent filters was pretty robust at that time. The prior device, one of the prior devices that the filter was modeled on was the Simon Nitinol, filter which was first used in 1990, so we had plenty of years of experience with permanent IVC filters. So our expectations were that this device would behave the same way as a permanent device. 01:30:57 01:31:19

Q. And what did that mean in centering, staying in position?

A. Well, what it meant as far as centering is difficult to say because some devices, as I've said already, had difficulty with centering. The Greenfield filter, which was another older device, had that issue. 01:31:37

As far as staying in place and not migrating, our expectations were that it would behave like the other devices and have a very, very low rate of migration. 01:31:55

Q. Was the expectation that if a patient received a permanent filter like the G2 when it was permanent that it would remain in the same position that we see here in Exhibit 4370 for the remainder and duration of the patient's life?

A. That expectation would be the same as what we had the expectations for the other permanent devices. Occasionally there were migrations of those devices but it was extremely rare. Reportable. 01:32:18

Q. And the expectation of the G2 when it was marketed as a permanent device? 01:32:34

A. Yes.
Q. Thank you.
I want to go up and look at some imaging. From what you saw on the imaging, did the G2 filter remain in the original position implanted in Sheri Booker? 01:32:50
A. No, it did not.
Q. And what is your understanding? You reviewed imaging over the years; correct?
A. Correct.
Q. And the purpose of the imaging that was done, was there imaging that was done for conditions that were unrelated to the G2 filter? Correct? 01:33:00
MR. O'CONNOR: Let's go to 4361. Excuse me. Let me make sure I've got that right. Hang on, Greg. That's the wrong one. I apologize. 4360, Greg. 01:33:32
BY MR. O'CONNOR:
Q. All right. Do you see the exhibit in front of you, Dr. Hurst?
A. Yes.
Q. What are we looking at? 01:34:14
A. This is an axial image of a CT scan that was performed on 6-26-14 so axial images for CT scans are basically an image that kind of cuts through the person horizontally like you're slicing a loaf of bread and this is just one slide of bread here. 01:34:36

Q. I'm sorry. What's the date of it? 01:34:37

A. 6-26-14.

Q. And why is that date pertinent to Sheri Booker?

A. This was the date she had a CT scan performed for pain in the right lower quadrant. 01:35:07

Q. And so you've reviewed this and you have actually identified certain findings on this Exhibit 4360; is that correct?

A. Yes.

MR. O'CONNOR: At this time, Your Honor, I would move for admission of Exhibit 4360. 01:35:22

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit Number 4360 was admitted into evidence.)

MR. O'CONNOR: And I would ask that it be published to the jury. 01:35:32

THE COURT: You may.

BY MR. O'CONNOR:

Q. Dr. Hurst, can you tell us what we are looking at, please.

A. Again, this is a CT scan of Sherr-Una Booker. It's the axial images of the upper portion of the abdomen which includes usually a couple of images of the heart. This is the heart on the axial study. 01:35:44

Q. And you had made some notations; is that correct?

A. Yes. 01:36:10

Q. Explain your notations and what you would like the jury to see here. 01:36:11

A. Sure. The notation on -- right here (Indicating) is just pointing out that that is the right ventricle of the heart so that right ventricle would look like this if it was x-ray dye in the blood vessels. But this is a non-contrast CT. 01:36:29

The other arrow is pointing at a linear or line-like metallic foreign body. Basically, it's a filter arm.

So this is an arm of the filter that broke off and migrated to the heart. So it would be one of these little guys right here (Indicating). 01:37:00

Q. And so, Dr. Hurst, that is very specific and I think I skipped one that we should probably look at before we get there. So let's look at Exhibit 4385. This imaging shows us the fracture in the ventricle of the heart; right? 01:37:33

A. Correct.

Q. Let's look at 4385. Doctor, can you identify this imaging study, please?

A. Yes. This is the scout view again of the abdomen from a CT abdomen pelvis that was done on 6-26-14. 01:37:55

Q. When you say scout view, what do you mean?

A. Again, this is a view of the abdomen that is obtained with the CT scanner to help the technologist choose their area of interest.

Q. All right. 01:38:14

MR. O'CONNOR: At this time, I would move for the admission of Exhibit 4385, Your Honor. 01:38:16

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit Number 4385 was admitted into evidence.) 01:38:24

MR. O'CONNOR: Move to publish to the jury, Your Honor.

THE COURT: You may.

BY MR. O'CONNOR:

Q. All right. Dr. Hurst, if you could explain to the jury what we're looking at and the significance of this imaging for your opinions, please. 01:38:29

A. Sure. So this image is a little fainter than the other scout view but I'm going to circle the filter right here (Indicating). This is the IVC filter and as you can see, the filter itself is now tilted off midline, basically parallel to the line that I've drawn. 01:38:46

Q. Are you able to outline the IVC?

A. Sure. The IVC would be expected to be like that (Indicating). 01:39:14

Q. And what else is important about this imaging that we're looking at?

A. So what it demonstrates is that the filter itself has moved from a position where it was up here in the inferior vena cava to down here approximately three centimeters from its 01:39:32

original position. So it's migrated towards the patient's feet. 01:39:39

Q. Is that a problem for a filter?

A. Yes. It can be a problem.

Q. Why is that a problem? 01:39:49

A. Because filter tilt leads to a cascade of events that can cause additional issues like penetration and fracture.

Q. Thank you.

MR. O'CONNOR: Let's go to Exhibit 4359.

Q. Can you identify Exhibit 4359, Dr. Hurst? 01:40:20

A. Yes. This is an axial view of the CT of the abdomen from 6-26-14.

Q. June 26?

A. Yes.

MR. O'CONNOR: Move for the admission of Exhibit 4359, Your Honor. 01:40:33

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit Number 4359 was admitted into evidence.)

MR. O'CONNOR: May we publish to the jury? 01:40:41

THE COURT: Yes.

BY MR. O'CONNOR:

Q. All right. Dr. Hurst, would you explain to the members of the jury why you selected this imaging and why this is important to talk about your opinions today? 01:40:54

A. So this image demonstrates one of the arms -- I'm sorry, one of the legs of the filter which is right here (Indicating), right there, that has penetrated outside of the inferior vena cava which is this structure right here (Indicating) and the arm is now penetrating into the large muscle of the lumbar spine called the psoas muscle. 01:40:58 01:41:22

Q. And what is the psoas muscle?

A. The psoas muscle is one of the main muscles that helps you lift your leg basically and it's also one of the main muscles of your back to help you maintain posture. 01:41:39

Q. Can a filter impinging in that area result in any type of symptoms?

A. Yes, it can.

Q. What types of symptoms?

A. It can cause back pain and it can cause radiating pain to the leg, especially with movement. 01:41:49

Q. All right. And is this strut, this leg, in a position where you, as an interventional radiologist, could reasonably expect that it would cause pain?

A. It would depend on the patient's clinical symptoms but if I saw this strut and the patient had symptoms like I described, I would be concerned that it was more likely than not that this was causing symptoms. 01:42:09

Q. Thank you.

MR. O'CONNOR: If we could move on, Greg, to 01:42:25

Exhibit 4386. 01:42:30

BY MR. O'CONNOR:

Q. All right. Dr. Hurst, can you identify this exhibit, please.

A. Yes. This is an axial image from a CT of the heart from 7-24-2014. 01:42:50

Q. And have you identified parts of this imaging that you want to help you explain your opinions to the jury?

A. Yes.

MR. O'CONNOR: Your Honor, at this time I would move for the admission of Exhibit 4386. 01:43:07

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

MR. O'CONNOR: I ask that it be published to the jury. 01:43:15

THE COURT: You may.

(Exhibit Number 4386 was admitted into evidence.)

BY MR. O'CONNOR:

Q. You made three labels here, Dr. Hurst. Can you walk us through them and what they are important for? 01:43:21

A. Sure. The first label is for the right ventricle which, again, is this structure right here. So this is the chamber of -- one of the chambers of the heart.

The second label is for the embolized filter arm so since this is an axial image and the slices of this scan are 01:43:47

really thin, you're only going to see a portion of that arm. 01:43:50

So what we're looking at here is the portion that is the most distal or most inferior in the heart. The tip of that embolized fractured arm is actually embedded in an important muscle in the part called moderator band. And that moderator 01:44:13
band, besides being a portion of the muscle of the heart that has to do with contraction, it also is basically the bridge for the electrical activity of the heart that travels through the septum of the heart and then to the right ventricle.

Q. You're showing us the tip. You are referring to what, the 01:44:36
tip of the filter?

A. Yes. The fragment right there.

Q. And is that a concerning finding?

A. Yes.

Q. Why is? 01:44:44

A. Well, just that location alone is concerning because of what I was just discussing, the conduction of the electrical current through the heart that keeps it beating, goes across that moderator band. So having the tip of the filter in that area could put the patient at significant risk for irregular 01:45:04
heartbeats and even a fatal arrhythmia, a fatal heartbeat.

Q. And then over to the -- you labeled something to the right. What did you write there?

A. It just says embolized filter arm.

Q. And you know we've heard migration. We've heard embolize. 01:45:22

When you use it as those terms as an intra -- as a radiologist, interventional radiologist, what do you mean by that term, embolization? 01:45:25

A. Embolization just means that there's some sort of free-floating body or more than body, like a piece of metal or even a clot that is going through the vascular system from one location to another. It's usually going from somewhere where it's okay for it to be to somewhere where it's not okay for it to be. 01:45:39

Q. Thank you, Dr. Hurst. And, again, what you've shown us today, you've selected imaging studies and just to summarize, what have they shown happened to Sheri Booker's G2 filter? 01:45:59

A. So Ms. Booker's filter tilted and then she developed penetration of the inferior vena cava by multiple arms. Those arms then either punctured or poked into adjacent organs which we did not show some of the films but the aorta, the bowel and the musculature which was -- we showed on that one image. The filter also subsequently developed fractures and the fracture fragment, one of the fracture fragments, migrated or embolized to the heard and lodged itself in the heart muscle. 01:46:22 01:46:50

Q. Okay. Thank you. I want to move to a different area and talk more about reasonable expectations. First I would like you to talk to us about informed consent and what is that concept and how is it important to you as an interventional radiologist? 01:47:12

A. So informed consent is basically a discussion that you have with a patient prior to doing a procedure or even giving them medications or any course of therapy. Basically, what it involves is a discussion of the risks of the procedure or the therapy, the alternatives to the therapy or the procedure, and the possible benefits. And in that discussion, you're helping that patient weigh the risks of their disease process, whatever they have, versus the risks of the treatment and you're helping them decide what is the right thing to do. 01:47:13 01:47:30

Q. So what does that mean when you're dealing with a device like an IVC filter? 01:47:55

A. So when operating physicians deal with medical devices, we kind of serve as your informant if you're the patient. We take all the information that we know about the particular device and its application and we take the disease process or the issues that the patient is having, we put those two together and we sort of do a risk-benefit analysis to decide whether the patient should get this device or another device or no device to treat their disease. 01:48:14

And that's all based on the risk profile of the device. The higher the risk of the device, the more benefit you better get out of it. The lower the risk of the device, you know, then you're willing to accept a lower benefit. 01:48:38

Q. So when you are looking at things like the risk profile of an IVC filter as an interventional radiologist, you have 01:48:58

expectations of a company like Bard? 01:49:03

MR. NORTH: Your Honor, objection. Cumulative of Dr. Streiff. That was one of his three main opinions last week.

MR. O'CONNOR: I'm asking him from the perspective of an interventional radiology and what his expectations are. 01:49:14

THE COURT: Hold on just one minute, please.

The objection is overruled.

THE WITNESS: Can you repeat the question?

BY MR. O'CONNOR: 01:49:33

Q. Sure. So when you talk about the risk profile, do you have expectations of the information that you will receive from a medical device company like Bard?

A. Yes. In order to perform informed consent properly to discuss the risks with the patient, you actually have to know what the risks of using the device are, what the possible dangers to the patient are. 01:49:47

Q. So what type of information do you expect to receive from a company like Bard to make that assessment?

A. Well, we want to receive information in regards to precautions for use. We want to receive information in regards to the incidence of events that occur, that are dangerous to the patient, that cause risk to the patient or that could cause bodily harm. 01:50:03

We also like to know the seriousness of the risks. 01:50:23

So there are some complications or risks of devices that are not really serious to patients. For example, we use vascular stents quite often in the blood vessels. If a stent fractures in a blood vessel, it's an event. It usually does not cause any significant outcome. 01:50:29 01:50:52

However, like an aortic valve, if an aortic valve fails, that's a significant event. The patient will likely die if the valve fails. So depending on the degree of seriousness of the event, we need to know both the incidence of the risk and how serious is that risk to the patient. 01:51:20

Q. If a company like Bard was representing and selling its product and representing that it had features like we talked about earlier, self-centering, but Bard internally was aware that its filter was having problems with self-centering, is that information that doctors like you would reasonably expect to receive from the company? 01:51:39

A. Yes.

MR. O'CONNOR: Your Honor -- Greg, can we display Exhibit 545?

Your Honor, this is in evidence. I would move -- may I display to the jury, please. 01:52:05

THE COURT: You may.

BY MR. O'CONNOR:

Q. Dr. Hurst, we're looking at an email dated February 27, 2004, and if you take a look at it and read it, can you tell us 01:52:18

if this is the type of information that you would have expected to receive from a company like Bard? 01:52:30

A. This is not the exact information that we would receive.

MR. O'CONNOR: Greg, if you could go down to the middle paragraph. 01:52:40

BY MR. O'CONNOR:

Q. So, Dr. Hurst, as you can see, there is a discussion here about the Recovery filter and it does not always stay centered in the cava. Do you see where I'm reading from?

A. Yes. 01:52:58

Q. Is that information that you would expect Bard to share with you as an interventional radiologist?

A. Certainly --

MR. NORTH: Objection. Cumulative of Dr. Muehrcke.

THE COURT: I think that same question was asked of him, wasn't it, Mr. O'Connor? 01:53:11

MR. O'CONNOR: But Dr. Muehrcke addressed questions as -- he was very specific as a cardiothoracic surgeon. This is an interventional radiologist who is dealing with these filters, implanting them and extracting them. 01:53:24

THE COURT: Well, he was doing the same. I'll let you ask this question but we need to limit the overlap for the benefit of the time of trial.

MR. O'CONNOR: Thank you.

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BY MR. O'CONNOR: 01:53:36
Q. Is this the type of information?
A. Yes.
Q. And did you -- were you told by Bard back when you were using the Recovery filter that there were concerns within Bard about the ability of this filter to stay centered? 01:53:41
A. No.
Q. Was that your experience after you were using the Recovery filter that, in fact, you learned that it was not staying centered? 01:53:58
A. Yes.
Q. And when you talk about the risk profile, the risk-benefit decisions that you have to make, help a patient with, is this the type of information that would have helped you help the patient make decisions about an appropriate filter? 01:54:11
A. Yes.
Q. And you would want a filter that was -- would you want a filter that was proven to be and tested to be self-centering?
A. Yes.
Q. Thank you. 01:54:23

MR. O'CONNOR: Let's go to Exhibit 932.

And, Your Honor, this has been admitted into evidence. May we display it to the jury?

THE COURT: Yes.

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BY MR. O'CONNOR: 01:54:50

Q. Exhibit 932 is entitled Bard Peripheral Vascular Filter Franchise Review. I take it this is not the type of information that you received as an interventional radiologist?

A. No. We do not receive this kind of information. 01:55:01

Q. But was it an expectation, a reasonable expectation of interventional radiologists that Bard would have tested and had an understanding of the anatomy, that is the dynamics of the vena cava, before it would release a filter to market?

A. We would expect any device manufacturer to do its due diligence and take reasonable care in design and production of the device. 01:55:19

Q. And why is understanding the caval dynamics important for a medical device company, Dr. Hurst?

A. Because the inferior vena cava is not like this tube. It is a hostile environment. The cava can collapse almost completely depending on the blood volume in your body. It can expand quite significantly depending on the blood volume in your body. It also is subjected to movement, you know, twisting, turning, pulling, stretching. Anytime you move, the inferior vena cava is going to move. 01:55:37 01:56:01

Q. And Dr. Hurst, was it -- now, back in May of 2008, the G2 filter was released and on the market; is that correct?

A. Yes.

Q. And was it a reasonable expectation that by that time that 01:56:19

Bard would have thoroughly tested and studied the cava dynamics before it released the filter to the market? 01:56:22

A. I would hope so.

MR. O'CONNOR: Go to 2867, Greg, of Exhibit 932.

I'm sorry. We must have two different copies. I want you to go forward six pages from the front, Exhibit 932. 01:57:07

MR. WOODY: What's the Bates number?

MR. O'CONNOR: The last three Bates numbers are 867.

Thank you.

BY MR. O'CONNOR: 01:58:03

Q. So, Dr. Hurst, we had a pause there while we were trying to get this exhibit up. But I think you told us that it was a reasonable expectation of the interventional radiology community that Bard would have had a thorough understanding of caval anatomy and had tested it and known enough about it so that they could release a safe filter; is that correct? 01:58:21

A. Yes.

Q. And as you look at Exhibit 932, what does that tell you about Bard's understanding?

A. The highlighted section says that there's a lack of thorough understanding of the dynamics of caval anatomy which impacts their testing methods. 01:58:38

Q. Is this something that you would have expected Bard to inform the medical community of at the time it released the G2?

A. I would expect them to either inform us or to have got a 01:58:56

further understanding before they released the device. 01:59:00
Q. Before they ever released it?
A. Yes.
Q. And certainly if Bard was aware of a -- that it had a lack of thorough understanding of dynamics of the caval anatomy, is 01:59:10
that information that would be important for you to know and in having that conversation with your patient, the informed consent process?
A. Yes.
Q. What would be important about that in terms of risk? 01:59:23
A. Well, if they don't have an understanding of the way the filter is going to behave in the inferior vena cava, then they are releasing the device that could be unsafe. They don't know either way whether it's going to perform as they intend it to or whether it's going to have an increased risk of 01:59:45
complications that could be dangerous to the patient or significantly -- or very serious.

MR. O'CONNOR: And let's take a look at Exhibit 991, please.

BY MR. O'CONNOR: 02:00:13
Q. Excuse me. Going back to that exhibit, the information that you just saw a moment ago, is that contrary to the reasonable expectations of interventional radiologists?
A. Yes.
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MR. O'CONNOR: Now go to Exhibit 991. And specifically I want you to go, Greg, to the last two paragraphs. 02:00:23

Q. If internally Bard was aware of complaints about the G2 and problems that it had about caudal migration, would you reasonably expect that the company would share that with you, Dr. Hurst? 02:00:47

A. Yes.

MR. NORTH: Objection, Your Honor. I think he's getting into an area of Bard by the *Daubert* order again. 02:00:57

THE COURT: I think you need to ask it in terms of the reasonable expectations of doctors, Mr. O'Connor.

BY MR. O'CONNOR:

Q. Would doctors, interventional radiologists, reasonably expect Bard to share and disclose information with them if it had information about complaints relating to the G2 as it related to caudal migration? 02:01:09

A. Yes.

Q. And if Bard had concerns itself that the G2, in terms of caudal migration, was worse than a predicate permanent device such as a Simon Nitinol filter, is that information that would be important to an interventional radiologist? 02:01:29

A. Yes.

MR. NORTH: Objection. I think that's across the line. 02:01:45

THE COURT: Overruled. 02:01:45

THE WITNESS: Absolutely, that would be important because in choosing a device for the patient, if you have an alternative device that is safer, you're going to choose the safer device. 02:01:52

BY MR. O'CONNOR:

Q. Do you think there's any reason that a doctor like you, an interventional radiologist who is treating patients who have serious medical conditions who need a device like a filter, is there any reason that you should have less information than the 02:02:05 medical director of Bard in terms of how the filter is behaving?

A. I think it depends on the information that is available. The medical director of Bard may have -- the information needs to be reliable. I guess -- if there's reliable information 02:02:28 that a reasonable physician would want, then that would be the information that I would want.

Q. So if Bard had concerns about complaints of one filter compared to another, is that information that you would expect them to develop and share with you in the medical community? 02:02:43

A. I think the key word there is develop. I think that I would expect them to further investigate what was going on and then when they had evidence of something going on or issues with the device, I think then that would be time to share.

Q. And you told us before that the Recovery device was out 02:03:03

before the G2 device; correct? 02:03:07

A. Yes.

Q. And what was your expectation of the G2 in relation to the Recovery? Was it your expectation that it would be as safe and have improvements? 02:03:17

A. Yes. As I said before, I mean, when we're looking at medical devices, our expectation is that there will be improved safety or effectiveness with the next generation of the device.

MR. O'CONNOR: Let's go to Exhibit 2052 and go to page 18, please. 02:03:40

BY MR. O'CONNOR:

Q. Just from the perspective of interventional radiologists, if Bard had information where it had compared complication rates between the G2 and the Recovery filter --

MR. NORTH: Objection. Cumulative. 02:04:04

THE COURT: Let's hear the entire question.

BY MR. O'CONNOR:

Q. -- and found that the G2 was worse than the predicate device, is that information you would want to know?

A. Absolutely. 02:04:15

Q. And so as you look at Exhibit 2052, assuming Bard had that internal information where it had some comparisons of trends of failure complications comparing the G2 to the Recovery filter, is that what physicians like you would have reasonably expected Bard to share with you in the medical community? 02:04:36

A. Yes. 02:04:40
Q. And what would you do with that information?
A. I would use it to help me decide what device to use in what situation with specific patients that I'm taking care of.
Q. And was this type of information shared with you? 02:04:50
A. No, we did not have this information.
Q. And when is the first time that you learned about this type of information that Bard actually had and that it had compared failure rates between its Recovery and its G2?
A. In this trial. 02:05:06
Q. Let's talk about an IFU. Would you explain to the jury what an IFU is?
A. An IFU is basically a document that comes with the package for the -- each device. An IFU stands for instructions for use. And it explains with diagrams and such how to use the 02:05:29 device, precautions that you need to take when deploying or using the device. It gives warnings for potential complications that can occur with the device. It basically is a piece of information that you can help use to decide whether or not to use a device and it helps you use the device itself. 02:05:52

MR. O'CONNOR: Let's display Exhibit 994.

Is this in evidence?

BY MR. O'CONNOR:

Q. Dr. Hurst, can you -- do you recognize what we're showing by Exhibit 994? 02:06:21

A. Yes. This is the instructions for use for the G2 filter system? 02:06:22

Q. Is this a document that you were using back when you were implanting the G2 permanent filter?

A. Yes. 02:06:32

Q. And are you familiar with it?

A. Yes.

MR. O'CONNOR: I move for the admission of Exhibit 994, Your Honor.

THE COURT: It's already in evidence, Mr. O'Connor. 02:06:39

MR. O'CONNOR: It is? Okay.

BY MR. O'CONNOR:

Q. Dr. Hurst, I want to talk to you about the IFU. What are the reasonable expectations of an interventional radiologist that a company will include in the IFU, the information for use 02:06:51 document -- instructions for use, excuse me.

A. So the instructions for use, we expect it to provide clear and accurate instructions for the use of the device and clear and accurate warnings for the risk of the use of the device and potential complications. 02:07:16

MR. O'CONNOR: May I publish Exhibit 994, please.

THE COURT: You may.

BY MR. O'CONNOR:

Q. In terms of Exhibit 994, the instructions for use for the G2 permanent filter, did this IFU meet the reasonable 02:07:31

expectations of physicians? 02:07:37

A. The IFU for the G2 filter provided a laundry list of complications of basically listing every single complication that could possibly occur with an IVC filter.

Q. Did it adequately inform you? Did it provide adequate information? 02:07:53

A. No. I don't think it did.

Q. Why?

A. Well, like I said, first of all, it basically provided a huge list of complications and warnings diluting out any specific warning that you could have gotten from it. In fact, the G2 IFU in comparison to the predicate device, the Simon Nitinol IFU, there were 32 I think, 32 warnings on the G2 IFU. There are four on the Simon Nitinol IFU. 02:08:07

The G2 IFU basically states over and over again that fractures are a known complication of filters. Tilt is a known complication without giving a rate or a degree of seriousness of the complication. By not giving a rate, in the interventional radiology world, we look at the IFU and we assume that when they don't give a rate, that's going to be a similar rate to the complications that we're used to with the prior devices. With the G2, I don't think that was what occurred. 02:08:36 02:09:05

Q. If a company like Bard didn't do a long-term clinical study, would you expect Bard to say so in the IFU? 02:09:20

A. Can you reword that, ask that question again? 02:09:28
Q. Sure. Let me ask you something differently.
If a company like Bard was aware that its filter had increased rates of failures compared to its own previous filters or other filters, is that information that you would 02:09:42
expect to see in an IFU?
A. Yes.
MR. NORTH: Your Honor, I'm going to object. I believe that's outside the scope of the report.
THE COURT: Is that in his report? 02:09:52
MR. O'CONNOR: He talks about the IFU in his report, Your Honor.
THE COURT: Well, can you show me where that is? We can take a sidebar.
If you want to stand up for a minute, ladies and 02:09:58
gentlemen.
(At sidebar 2:10.)
MR. O'CONNOR: He talks about the IFU there.
THE COURT: Well, the question is --
MR. O'CONNOR: He has opinions about warnings and the 02:10:41
IFU is a form of warning.
MR. NORTH: I'm sorry, Your Honor. Number two?
THE COURT: Page 12, paragraph two. This doesn't --
MR. NORTH: It does not address clinical studies is my point, Your Honor. 02:11:25

MR. O'CONNOR: And I'm talking about increased rates of failure. 02:11:26

THE COURT: Let me look at the question.

The question is whether -- if the filter had increased rates of failure compared to its previous filter, is that something you would expect to be disclosed in the IFU? Where do you think that is? 02:11:54

MR. O'CONNOR: Well, he talks about the IFU here but he's talking about warnings and the information, what reasonable doctors would expect. 02:12:11

THE COURT: Where does it talk about increased rates of failure?

MR. NORTH: Your Honor, if that's the question, I must have misunderstood. I thought it did -- I mean, I thought -- 02:12:21

THE COURT: Well, he then reworded the question.

MR. NORTH: And I'm sorry I didn't catch that. I'll concede on page ten he does. I apologize.

MR. O'CONNOR: Did we get an answer to it?

THE COURT: Thank you, ladies and gentlemen. 02:12:34

(End of sidebar discussion.)

BY MR. O'CONNOR:

Q. Dr. Hurst, I think the question was, if Bard had information where its G2 filter -- Bard was aware that the G2 filter had increased rates of failure compared to its own 02:12:59

filters, the previous filters or other filters, is that information that you and members of the medical community would expect to see in the IFU? 02:13:05

A. Yes.

Q. And is it in the IFU? 02:13:14

A. No.

Q. When you talk about reasonable expectations in this case, Dr. Hurst, do you have an opinion whether the G2 that Ms. Booker received performed as a reasonable physician and patient would expect it to perform? 02:13:36

A. It did not perform the way you would expect a permanent filter to perform.

Q. And explain the basis of that opinion. What happened to this filter?

A. The filter tilted. It caudally migrated or moved towards the patient's feet. It penetrated the inferior vena cava with multiple legs and arms poking into or perforating adjacent structures. It developed three structures, one of which the fracture fragment migrated to the heart, embedded in the heart muscle and required open heart surgery to remove. In addition, the filter tilted and there were fracture fragments at the site of the filter that required an extensive percutaneous removal technique. 02:13:47 02:14:18

Q. And those combination of failures and the type of surgery, including the complex open heart procedure that Ms. Booker had 02:14:41

received, are those contained in the IFU? 02:14:47
A. There is no discussion of the fact that the filter -- actually, can I take a quick look at the IFU?
Q. Sure.
A. Can I look at it on my computer? 02:15:06
THE COURT: Yes. Is there an easier way for you to get it?
THE WITNESS: I can barely read this one.
THE COURT: That's fine.
THE WITNESS: It will take me a second. I've got it. 02:15:16
Okay. So can I hear your question again?
BY MR. O'CONNOR:
Q. Sure. And I'm just going by something -- you prepared a report in this case; correct?
A. Yes. 02:15:54
Q. And just so we're clear, you have been compensated for your time to come here today?
A. Yes.
Q. And how much do you charge?
A. $500 an hour. 02:16:01
Q. And my question to you is this: Do you have an opinion whether Sheri Booker's filter performed as a reasonable physician and a reasonable patient would expect it to perform?
A. It did not.
Q. And the basis for that opinion is what, Doctor? 02:16:18

THE COURT: I think he just answered that question, Mr. O'Connor. 02:16:21

BY MR. O'CONNOR:

Q. And you talked about the combination of failures that the G2 filters experienced in Sheri Booker; is that correct? 02:16:27

A. Yes.

Q. And you talked about the complex procedure that she underwent?

A. Yes.

Q. Is that combination, that constellation, the cascade, is that indicated in the IFU? 02:16:38

A. The IFU lists -- like I said, it is a list of basically every single complication that could possibly occur with a filter.

So in that fashion, yes, those complications are listed here. However, the incidents or the rate at which those complications occur and then the seriousness of the complications are not listed in here. 02:16:58

Q. If Bard was aware that a failure complication like migration and tilt led to other complications such as perforation and fracture, is that information that you would reasonably expect a physician like you would reasonably expect for Bard to share with the medical community? 02:17:16

A. Yes.

Q. And is that the type of information that should also be 02:17:32

included in documents where Bard is talking about and warning of complications? 02:17:36

A. Yes, and they should include also the potential seriousness of the complication. So if a filter fractures and the fragment doesn't go anywhere, which we've seen with the other devices like the Simon Nitinol filter, if the filter fragment just stays right where the filter is, it may not cause a problem for the patient. 02:17:52

But with this device, the way that it was designed, these arms are only attached to the filter tip. They don't attach to the wall. They don't attach to anything else, just the filter tip. So if a fracture occurs, those arms are more likely to go somewhere because they are not attached to anything. 02:18:11

So the seriousness of a fracture in this device versus this device (Indicating) is way more because this fragment is going to go to the heart or it's going to go to the lungs and it's going to cause a problem. 02:18:29

Q. And is that information that you expect Bard to share with the medical community? 02:18:47

A. The degree of seriousness of the complications, yes.

Q. And when you were using this filter, did Bard share information about the seriousness of complications that were inherent in the G2 filter?

A. No. What the IFU does is just describe the fracture as a 02:19:00

known complication, so my assumption would be it's the same kind of fracture that we would see with the Simon Nitinol or the Greenfield. 02:19:06

Q. You would expect more?

A. I would expect more, yes, if they knew that that was occurring. 02:19:18

Q. And did you receive that information?

A. No.

Q. Your opinions today, have they been to a reasonable degree of medical certainty? 02:19:31

A. Yes.

Q. Have we covered your opinions?

A. Yes.

Q. Thank you.

MR. O'CONNOR: That's all I have, Your Honor. 02:19:39

THE COURT: Cross-examination?

MR. NORTH: Yes, Your Honor.

CROSS - EXAMINATION

BY MR. NORTH:

Q. Good afternoon, Dr. Hurst. 02:19:56

A. Hello.

Q. I believe you and I have met on a couple of occasions in Cincinnati where I took your deposition; correct?

A. Yes, sir.

Q. Now, you testified in response to some of Mr. O'Connor's 02:20:03

questions that you believe that if a company has reliable information about the performance of its device, it needs to share that with physicians; correct? 02:20:07

A. Especially if it has to do with complications, yes.

Q. But I believe you also said, in response to Mr. O'Connor's questions, that you believe that a company should investigate, be investigating if there are reports of complications; correct? 02:20:21

A. Well, I think that there's a fine line between, you know, the amount of investigation that has to occur and the caution or warning that has to be put out. 02:20:39

So what occurs with medical devices is that you expect a company to have a surveillance program, to be vigilant once they have released the device, especially if there's concern that there may be different behavior of that device in comparison to its prior devices. 02:21:03

So to answer your question, I think that you do need reliable information; but if there are multiple reports of adverse events coming in, that sort of information needs to be communicated to the general interventional radiology public. 02:21:27

Q. And I don't think you and I disagree. But if the information is just starting to come in or some information is and the company is just beginning to investigate and doing so promptly but has yet to have sufficient reliable information to make any conclusions, you wouldn't expect them to go warn 02:21:48

physicians on preliminary information, would you? 02:21:53
A. Well, I would not expect them to warn physicians. However, in this particular device, the device prior to it, the Recovery filter, there were also similar complications.
So they had, you know, two or three years to evaluate 02:22:11
the device before this device and form some opinions on issues or complications and risks.
MR. NORTH: Could we look at Exhibit 2052?
And, Your Honor, this has been admitted I believe.
Could we publish it? 02:22:35
THE COURT: Yes.
MR. NORTH: Turn to page 18 if you would.
BY MR. NORTH:
Q. Mr. O'Connor showed you this page of this document beforehand; correct? 02:22:49
A. Yes.
Q. And he suggested to you that this was reliable information concerning the complication rates of the G2 that should have been provided to physicians; correct?
A. I'm not sure if he said the word "reliable" but, yes, he 02:23:00
did submit it as information.
Q. And in giving your opinions regarding this document, you considered it should be reliable investigating information; correct?
A. Actually, I think -- I'm not exactly sure what I said but 02:23:13

I think I actually said that if this was information that Bard had, that it would be important for physicians to know. 02:23:16

Q. If we could turn to page two. Are you aware, Dr. Hurst, that the data that Mr. O'Connor showed you and that we just saw was based on 56 adverse event reports out of 100,000 plus G2 and G2X filters sold? 02:23:44

A. Yes.

Q. That's a very small sampling from a very large number; correct?

A. Correct, but it was early on in the experience of the device. 02:23:59

Q. But that is preliminary information. Wouldn't you agree? If you only had 56 events out of 100,000 plus sold?

A. I believe the Simon Nitinol filter had much less than that over many, many more devices sold. 02:24:15

Q. Well, let me ask you this, Dr. Hurst. You have told us previously when you were deposed that you would consider a migration rate less than one percent to be acceptable with a filter; correct?

A. I did say that in my deposition, yes. 02:24:32

Q. And you have said that you would consider a fracture rate with any filter less than one percent to be acceptable?

A. I did say that but I would like to qualify that and I want to get back to what I meant or what I was saying about the seriousness of the complication. 02:24:50

So you're right, a fracture rate of less than one percent is pretty good for a filter but it's only pretty good for these permanent filters where there are -- where there's at least one attachment point for a fractured component. 02:24:52

When you deal with this filter, you've got one attachment point and if that breaks, this arm is gone. 02:25:12

Q. And you told us earlier that you would consider a tilt rate less than one percent with any inferior vena cava filter to be acceptable?

A. Again, you have to qualify that -- 02:25:39

Q. Are you able to answer it yes or no?

A. Yes. Yes, I did say that. But I would like to qualify the statement by saying when you asked that question -- when we deal with this type of filter, a conical filter like the Greenfield filter, tilt is almost expected. The tilt rates for 02:25:56 this filter are much higher than with the Simon Nitinol filter.

So if you're going to put all of the filters together, you're going to get a rate that is a combination of this filter, which tilts quite a bit, and this filter which barely tilts at all. 02:26:17

So one percent for all of the filters is probably pretty good, but the issue with this device is that it doesn't just tilt. When it tilts, it sets off a cascade of events that include penetration and fracture and eventually embolization of fragments. 02:26:38

Q. And didn't you tell us earlier in your deposition that you agreed that a perforation rate less than one percent is acceptable with an inferior vena cava filter? 02:26:39

A. Yes, I did say that. Again, you have to qualify that statement. Each one of these filter devices, and there are at least five or six more permanent devices that have been around for a long time, each one of them had its own weakness, either one or two weaknesses. The Greenfield filter we talked about used to tilt. Occasionally it would get some fractures and also some penetrations but not -- it would not penetrate as high -- at as high of a rate as this filter which is the Simon Nitinol filter. This filter had a high rate of penetration but a fairly low rate of fracture and certainly a low rate of migration after implantation. 02:26:57 02:27:19

Q. I understand the qualifications that you are offering today but would you agree that when asked these same questions at your deposition, you agreed that a rate, a perforation tilt, fracture, or migration less than one percent would be acceptable with any inferior vena cava filter and you did not offer those qualifications at that time? 02:27:43 02:28:02

A. I didn't offer those qualifications at that time.

Q. So if you would again look at page two of Exhibit 2052 and out of 100,000 units sold as of that time, the number of adverse events reported was .06 of one percent; correct?

A. So they got that number by dividing 56 by 100,826. Is 02:28:39

that what I'm supposed to understand? 02:28:45

Q. Yes.

A. So 56 is the total number of adverse events that were reported?

Q. Yes. 02:28:52

A. Correct.

So when we look at adverse events, they are reported by physicians voluntarily so if you're using a medical device and you, unfortunately, happen to have a complication with a medical device, you are supposed to voluntarily report the 02:29:10 adverse event to the FDA and that is how this MDR number 56 comes up.

The issue is that physicians are busy. They don't report these device adverse events so we know that this reporting number is low. 02:29:31

This second number, the number on the bottom, the 100,826, is actually a total number of units distributed. So I don't think we know exactly how many filters are implanted out of those units distributed. So that number overestimates the denominator. 02:29:53

Q. Wouldn't you agree with me that these devices cost money; correct?

A. Yes.

Q. And hospitals are not going to buy a large surplus of these filters and just leave them on the shelves, are they? 02:30:04

A. The expiration date for the G2 I think was a year at least and, to be honest, actually, we do buy a lot of devices, especially if we have difficulties with deliveries or if we're afraid a device might have a recall or there's issues that we've had with the rep or salespeople before. So sometimes we'll buy up to 50, 60 devices. 02:30:08 02:30:27

And at that time also we weren't buying the devices. Most of them were on what we call consignment so they would just deliver 20 devices, put them on our shelves and then we would pay them -- pay for them after we had used them. 02:30:45

Q. But my point is, wouldn't you agree that well more than 50 percent of the units sold were -- knowing the business field as you do, were probably utilized?

A. I would say somewhere between 50 and 75 percent, yes.

Q. Okay. 02:31:03

THE COURT: We're going to take a break at this point. We will resume at a quarter to, ladies and gentlemen.

We'll excuse the jury.

(Jury departs at 2:31.)

(Recess at 2:31; resumed at 2:44.) 02:31:33

(Jury enters at 2:44.)

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you. Please be seated.

You may continue, Mr. North.

Ladies and gentlemen, by the way, we'll go to 4:20. 02:45:37

Go ahead, Mr. North. 02:45:40

MR. NORTH: Thank you, Your Honor. If we could display I think it's 2052 again that we were looking at right before the break. Page two.

Q. So you said it was a fair estimate of between 50 and 75 percent of units sold would probably be actually implanted in people? 02:45:59

A. I think so. I mean, I don't know if we can exactly find a number from -- I don't really know.

MR. NORTH: If we could use the document camera. 02:46:27

BY MR. NORTH:

Q. So, Doctor, if we have 100,826 units sold as of this time and you said between 50 and 75 percent -- let's be conservative and assume 60 percent being implanted.

A. Okay. 02:46:48

Q. By my calculation, that comes up to 60,495.6 but we'll just do it with a whole unit here. Does that sound right to you?

A. Sure, that sounds fine.

Q. Now, you also said that the adverse events were underreported correct? 02:47:12

A. Yes.

Q. And at that time, in 2008 when these numbers were there, the adverse events were 56; is that correct?

A. Correct. Those are the reported adverse events, yes. 02:47:31

Q. Okay. Let's assume for a moment that that is doubled to 112. 02:47:37

A. And where are you getting that number?

Q. Just a 100 percent increase for the sake of argument.

A. Okay. I've seen worse than that. I mean, I've seen numbers where the percent that is reported is approximately one to two percent. 02:47:55

Q. Have you not also seen reports that show it at much more also?

A. No, I haven't but they may exist. 02:48:17

Q. And you are not an epidemiologist?

A. I am not.

Q. And you have not been trained in that field?

A. No, I am not a trained epidemiologist.

Q. So let's just assume for the sake of argument 100 percent increase and let's say that Bard had received as of this point 112 as opposed to 56 reports of adverse events, so that would be our numerator; correct? 02:48:29

A. Yes.

Q. So the numerator would be 112 adverse events. And based upon what you were telling us earlier or what we were computing earlier, let's do a reduced number for the denominator. That would be the denominator; correct? 02:48:52

A. Sure.

Q. What sort of rate does that come up with? Can you do that 02:49:23

math? 02:49:26
A. Not in my head. Can you?
Q. You're the scientist. Do you have something there you could do it for us?
A. I can figure it out if you want here. 02:49:33
Q. You would be a much better bet than me.
A. 112 divided by 60,000 -- what did you get, 60,495. So 00185., so .18 percent.
Q. Obviously, Dr. Hurst, completely changing these assumptions, reducing the number of units sold by 40 percent, 02:50:14
doubling the number of reports, the reports of adverse events to Bard as of that date in 2008 in Exhibit 2052 are only .0018 percent; correct?
A. Correct. You know, what's interesting about what we're doing here is we're making gross assumptions of what the events 02:50:38
reported rate is and gross negligence assumptions of what the units sold means versus the units used means versus the units that are causing an event at that time. I mean, this was only two or three years into -- what is the date on that document? It's only two or three years into the filter and Ms. Booker's 02:51:06
failure didn't fail for four or five years or even six. So it seems to me like there would be a better way to measure adverse events, perhaps a real study, you know, a clinical study where the patients are consented, a registry, some way of following these patients in a systemic fashion instead of guessing at the 02:51:35

numbers.
Q. Well, let me ask you this. Assuming that you're correct and we're making gross assumptions and we're already made some assumptions to reduce the number of units by 40 percent to double the number of adverse events by 100 percent, let's assume, as you say, that those are gross assumptions and let's just assume that the rate is ten times what we computed there.
A. What you're computing here is just number of adverse events. You're really not computing the seriousness of the events which I discussed earlier. A simple fracture where there's no migration of the fragment, a migration where there's no penetration or interaction with the aorta or the pancreas or the bowel, you know, this doesn't take into account the degree of seriousness. I mean, your level of tolerance for a complication, if it's a serious one that could result in death, is one out of a million.
Q. But the fact of the matter is even after reducing the numbers that Bard had significantly and because of those gross assumptions, you started out, even after we made those reductions of .0018 percent, you multiply that, let's assume it's ten times greater, even then it's only 0.18 percent; correct?
A. Your math is fine, yes.
Q. Thank you. Rare that's been said.
And that is way less than one percent; correct?

A. It's way less than one percent, yes. 02:53:33

Q. Thank you, sir.

You have testified that at some point Ms. Booker's filter caudally migrated, tilted, perforated and then fractured; correct? 02:53:50

A. Yes.

Q. What's the earliest point in time that you observed that complication?

A. Let me look at my report here just to make sure that we're on the same page. 02:54:00

Q. And if I could help you to speed this along, maybe the bottom of page five.

A. Yes. 2-20 -- 2-24-08.

Q. So in February of 2008 there was radiographic evidence on these scans that the filter had migrated, tilted, perforated and fractured in your view? 02:54:29

A. Yes.

Q. And the doctors did not assess that situation and identify it until 2014; correct?

A. That is correct but in that time, diagnostic radiologists were used to visualizing these types of devices, these permanent filters, on CT scans. In fact, I don't know of a whole lot of papers that were published at that time that described the, quote, complications or that you should see on CT related to this new class of filters, the retrievable 02:54:45 02:55:09

filters.

So I don't think that general radiologists, diagnostic radiologists who were not trained in vascular interventional radiology, were even aware of the change in devices. And certainly they were not looking for the complications that could occur with this kind of device. 02:55:16 02:55:29

Q. You're aware of the fact that Ms. Booker, before she had a G2 Filter implanted, suffered a pulmonary embolism on two occasions; correct?

A. Yes. 02:55:46

Q. And you're also aware that in the seven years after she received the filter she never had a pulmonary embolism?

A. That is correct.

Q. Now, when we took your deposition in July of last year, 2017, you told me that at that point, you had actually implanted in one of your own patients a Bard filter within the last two months; correct? 02:55:59

A. Yes.

Q. And have you implanted any Bard filters since July of 2017? 02:56:15

A. So I currently --

Q. Could you answer the question yes or no?

A. Yes, I have, in fact, two weeks ago. So I currently use the Bard Denali retrievable filter. Since using these devices, the Bard Denali Filter is the most current iteration of these 02:56:33

devices. After they experienced the complications and issues with these devices, they made serial changes over each generation of device, like four generations, after they got their data back from patients who did not consent to having -- being experimented on, they made serial changes to the filter such that they corrected the majority of the issues with this generation of filter. 02:56:38 02:56:58

So I use it solely as a retrievable or temporary device. My patients I follow religiously with imaging if necessary, if it gets past three months, and I remove the filters usually before three months. I only use it for a temporary indication. If I'm going to use a permanent filter, I use what's called a VenaTech filter. 02:57:21

Q. And we talked earlier about acceptable rates of complications in your view. You would agree with me that all inferior vena cava filters migrate, fracture, tilt, and perforate on occasion; correct? 02:57:41

A. On occasion, they do.

Q. Now, you testified earlier, and I thought you said that G2 fractured struts always go to the heart or lungs. Is that your opinion? 02:57:58

A. Oh, no. I didn't say that. I misspoke. They don't always go to the lungs or the heart.

Now, if they are going to embolize, if a fracture fragment is going to move through the vascular system, the next 02:58:14

location for it to go is to the heart or lungs. 02:58:17

But fracture fragments can actually pass through the wall of the inferior vena cava and enter into the duodenum, which is the bowel, and actually be passed through the bowel. I've seen that. They can also pass into the urinary tract into 02:58:36 the ureter, which is the tube that carries urine from the kidney to the bladder, and it's close to the inferior vena cava or they can be trapped in the retroperitoneum. So they can be in multiple locations, the fragments can, and they can move.

Q. And in many occasions or many instances, the fractured 02:58:56 struts simply become encased in the tissue of the inferior vena cava and go nowhere; correct?

A. Correct. They can become encased in the inferior vena cava tissue, yes.

Q. And in fact, that's the case with the one strut that is 02:59:12 retained in Ms. Booker's body; correct?

A. Actually, I think a portion of that strut is outside the inferior vena cava because she has a reactive -- it's called an osteophyte. Basically, the point or the tip of the -- this leg that is fractured is actually interacting with the vertebral 02:59:31 body or the bone of the spine that's right behind the inferior vena cava.

So I'm pretty sure actually that that -- at least a portion of that fragment is outside of the inferior vena cava.

Q. But it is immobilized; correct? 02:59:49

A. Not necessarily true. These fragments are sharp by nature. You know, the filter itself has to penetrate, at least the foot does into the inferior vena cava wall when it's deployed so it will hold on. It's a little hook. So it's sharp. So they can move. 02:59:53 03:00:08

I don't think we know the answer to your question.

Q. You've seen no evidence that that strut has moved in Ms. Booker in the four years since it was located, have you?

A. I have not. It hasn't moved.

Q. And are you aware of the fact that the literature reports that as many as 95 percent of the cases where a filter fractures, it is an asymptomatic event, i.e., the patient does not have pain or other symptoms accompanying that fracture? 03:00:26

A. I have seen literature that states that but I've also seen literature that shows that there are a higher percentage than that that are symptomatic. 03:00:45

Q. But you would agree, regardless of where you peg that percentage in your view, that a significant number of fracture events are asymptomatic?

A. I would agree with that statement. However, the issue again is the -- a fracture fragment that doesn't move and is asymptomatic I agree is not an issue for a patient. But if a fracture fragment goes to the heart, that becomes a big issue for the patient. It's a serious issue that could require open heart surgery, could require -- could cause an arrhythmia, 03:01:02 03:01:21

could cause death. 03:01:25

So it doesn't really matter what that percentage is. It matters what the seriousness of the complication is that arises when that fracture fragment migrates.

Q. And you would agree that tilt can often be an asymptomatic event? 03:01:40

A. Yes. Tilt can be an asymptomatic event.

Q. As can caudal migration?

A. Correct. These are all part of the cascade of events that occurs with the G2 filter. 03:01:53

Q. And penetration can be an asymptomatic event; correct?

A. Yes, it can be.

Q. Now, talking about migration a moment, you would agree with me that cephalad migration, toward the heart, is a much more dangerous event usually than caudal migration downward? 03:02:10

A. When we talk about cephalad migration, we talk usually about the whole filter moving towards the heart and actually maybe even into the heart. That was a characteristic of the device that was prior to this, the Recovery device. The G2 filter was the device that came after the Recovery and they made modifications in this device to decrease or significantly attempt to decrease that risk of migration to the heart of the whole filter when it got hit by a clot. 03:02:31

But I think the unintended consequence was that by making these legs longer and wider, they got more penetrations 03:02:55

and they got this tilt issue. 03:02:58

Q. Well, you were aware of deaths reported in the literature with various manufacturers' filters migrating to the heart; correct?

A. Yes. 03:03:14

Q. And you're not aware of any death reported in the literature from a caudal downward migration of a G2, are you?

A. No, not from specifically from the caudal migration, no.

Q. Now, you mentioned just a moment ago that if the filter migrates to the heart, I mean, the filter strut migrates to the heart, it can necessitate open surgery? 03:03:36

A. Yes.

Q. Open heart surgery. You were deposed just a couple of weeks ago by one of my partners, Mr. Brown, weren't you?

A. Yes. 03:03:50

Q. And I believe you --

MR. O'CONNOR: Objection, Your Honor. May we approach?

THE COURT: Yes, you may.

You can stand up, ladies and gentlemen, if you would like. 03:03:59

(At sidebar 3:04.)

MR. O'CONNOR: We have an agreement that these depositions that are going in state court cannot be used in this trial. That was our agreement with Mr. Wenner. I think 03:04:15

it would be improper for him to go into a deposition that he just gave for a state court case two weeks ago, has not been disclosed. 03:04:19

MR. NORTH: I am totally unaware of that agreement but I will respect you in reporting that and I'll just move along. I'm sorry. I did not know of that. 03:04:27

MR. O'CONNOR: And I don't want to misrepresent or mislead anybody but I know there were discussions with Mr. Wenner --

MR. NORTH: Okay. I'm conceding the point. I just don't know. 03:04:40

(End of sidebar discussion.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. NORTH:

Q. Dr. Hurst, my understanding is you charge $500 an hour to review documents and records? 03:05:09

A. Yes.

Q. And my understanding is that you were furnished 20 to 25 Bard documents by the plaintiffs in this case; is that correct?

A. In this specific case, 20 to 25 but I have more documents that were supplied in a separate case that I've also been able to look at and also there is a dropbox that has many more documents than that. 03:05:24

Q. But you have not spent time going through the dropbox, have you? 03:05:40

A. I have not. I've reviewed the expert witness reports of Parisienne and Kessler and they go through those documents pretty thoroughly. 03:05:40

Q. Now, you charge more when you're giving a deposition. I believe you charge $750 an hour? 03:05:56

A. Yes.

Q. And when you are traveling, as you are today from Cincinnati, you charge $6,000 a day; is that correct?

A. $3,000 for half day, $6,000 for a whole day.

Q. And for how many days will you be charging the plaintiffs in this case, two or three? 03:06:11

A. Two.

Q. So you're charging $12,000 for your trip out here?

A. Yes.

Q. Would you think it's fair to say that you've charged the plaintiffs in excess of 20 to $25,000, you will have, by the time you finish testifying here for this case? 03:06:20

A. Absolutely, yes.

Q. Now, I believe you testified earlier that you believed in the IFU or the instructions for use, the warning given to doctors, there should have been some indication comparing rates; is that correct? 03:06:59

A. I believe that I said something about that I would like to see the rates. I didn't necessarily say you had to have a comparison of one rate versus another. In other words, when 03:07:17

you're looking at the IFU and there's no number on there, okay, so let's say there's a known complication of fracture, my assumption and other physicians, I would expect their assumption would be that that rate is going to be similar to the known rate of other devices prior to that device. 03:07:22 03:07:38

Q. You have never seen any medical device manufacturer include comparative rates, complication rates in an IFU, have you?

A. There are no IFUs that I have seen that would put comparative rates in the warning section or the precaution section. Many IFUs, though, do have their preliminary safety study published in the IFU, at least the data from the safety study. 03:07:59

Q. Did Bard's IFU for the G2 have any data from a preliminary study? 03:08:17

A. It did.

Q. Exactly what you're talking about here?

A. Binkert trial, B-I-N-K-E-R-T. The EVEREST trial.

Q. And it published data in the instructions for use about that study; correct? 03:08:33

A. It did.

Q. And it also published data in the instructions for use for the doctors about adverse events that had been reported as a part of that study, didn't it?

MR. O'CONNOR: Objection, Your Honor. Irrelevant. 03:08:47

We're talking about a very specific IFU in this case. 03:08:48

THE COURT: Overruled.

THE WITNESS: So repeat your question. I'm sorry.

BY MR. NORTH:

Q. The discussion of the EVEREST study in the IFU, the instructions for use for the G2 filter included data regarding adverse events that had been reported during the EVEREST study; correct? 03:08:59

A. It did, yes.

Q. And you wouldn't want any complication data in these IFUs, would you, unless it was reliable? 03:09:18

A. That is correct, yes, I would want reliable data. The other thing that the instructions for use did not provide that I think would have been important would have been some sort of direction for how long this device could be left in a patient. 03:09:39

The IFU did not discuss when it was appropriate to take this device out. Now I realize the G2 was not even approved for retrievability at that time but when the final IFU came out, there was still no recommendation for the length of time that this device could be left safely in a patient. 03:10:07

Q. Isn't the time that the device should be left in a patient a case-by-case determination by the treating physician?

A. In some regards, yes. However, that's if you're using a retrievable device. But if you want the device to be permanent, it's permanent. 03:10:29

Q. Some patients will need the device for only a few weeks or months; correct? 03:10:36

A. Correct.

Q. And have a short-term need for the device?

A. That is the appropriate use of a retrievable device in the current standard of care. 03:10:44

Q. And some patients will need a longer period of time because of a history of pulmonary embolism and a contraindication to anticoagulation; correct?

A. And those patients receive a permanent device. 03:11:00

Q. And that, again, is a patient by patient determination by the doctors treating that patient; correct?

A. Correct, but the current practice is if a patient has a pulmonary embolism and can't receive anticoagulation and you think it's going to be a temporary situation where you're going to be able to put that patient on blood thinner medicine, which is safer than a filter, you're going to put them on blood thinner medicine maybe three months from now or two months from now, you can put a retrievable filter in and then your plan is to take it out within two to three months once their contraindication to blood thinner passes. 03:11:20 03:11:38

In practice right now, if that time starts to get out past three months, four months and the patient still needs a filter, our practice is to take the temporary filter out usually a Günther Tulip or a Bard Denali filter, and put in a 03:12:01

permanent filter like the Greenfield or VenaTech or -- we can't put the Simon Nitinol filter in because it's not available any more. 03:12:06

Q. And in this particular case, you're aware of the fact that the filter, G2 filter, had just been cleared for permanent use at the time it was implanted in Ms. Booker correct? 03:12:16

A. Yes.

Q. But you're also aware that her physician wanted a filter that he knew could be retrieved if he wanted to; correct?

A. I think that's what his deposition says, yes. 03:12:32

Q. And there is no reason after she completed her surgery, some period of time after that that Ms. Booker's doctors would not have called her back in and returned her to anticoagulation and retrieved the filter percutaneously; correct?

MR. O'CONNOR: Objection, Your Honor. Irrelevant and lacks foundation. 03:12:52

THE COURT: Overruled.

THE WITNESS: So -- I'm sorry. Repeat the question again.

BY MR. NORTH: 03:13:07

Q. In Ms. Booker's case, she was given the filter because she had to be removed from anticoagulations so she could have the surgical procedure related to her cervical cancer; correct?

A. Correct.

Q. And once that surgery and her Recovery was completed, her 03:13:17

physicians could have restarted her anticoagulation and retrieved that filter percutaneously, couldn't they? 03:13:21

A. They could have, yes. It would have been outside of its use but -- its current instructions for use but yes, they could have. 03:13:41

Q. And the doctor who had implanted it always had the intent of being able to do that by his deposition testimony; correct?

A. I think so, yes.

Q. Thank you, Doctor. That's all I have.

THE COURT: Redirect? 03:13:50

REDIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Are you good at math?

A. It's not my strong suit.

Q. Well, I'm bad. But here's what I'm told. Let's go to Exhibit 2052, page two. This is where we got started I thought -- first of all, Dr. Hurst, this exhibit and this page on this exhibit, how many different failure modes is it dealing with? Is it just dealing with fracture? 03:14:34

A. This one is just dealing with the single failure mode which is fracture, that is correct. 03:15:38

Q. And the issue that you were talking to this jury about the G2 filter had more to do than just with failure modes than just fracture; is that correct?

MR. NORTH: Objection, leading. 03:15:54

THE COURT: Sustained. 03:15:55

BY MR. O'CONNOR:

Q. What is the problem with the G2? Is it limited to a single failure mode?

A. No. Like I discussed before, the prior filters each had 03:16:01
their own weakness, usually one weakness, whether it was fracture, migration, tilt. But the G2 had multiple weaknesses, multiple modes of failure: Tilt, fracture, migration, embolization of fracture fragments, so it's the combination of the modes of failure that makes the device unique. 03:16:30

MR. O'CONNOR: And so may I publish this to the jury, please, Your Honor?

THE COURT: Yes.

BY MR. O'CONNOR:

Q. Is this a good way to evaluate failure rates in your opinion? 03:16:50

A. I don't. As you can see by the way we were messing with the math and the disagreements about units distributed and units used and complaint rates and MDRs and things like that, it is not a reliable way to track complications. A more 03:17:14
reliable way to evaluate a device would have been a registry trial or a true clinical trial once they thought they were having complications.

Q. All right. We'll talk about that in a moment. But Dr. Ciavarella -- you heard that name. We talked about him on 03:17:32

your direct? 03:17:36

A. Yes.

Q. He was a Bard medical director. Are you aware of that?

A. Yes.

Q. I want you to assume Dr. Ciavarella testified that when it relates to underreporting of adverse events, that probably only one to five percent are actually reportable. It's actually out there. Does that make sense to you? 03:17:41

A. Yes, it does make sense.

Q. And when you look at the math -- and I am absolutely the wrong guy to talk about math but here is Mr. North's math and when you divide 60,495 into 112, what do you get? 03:17:58

A. .0018 percent.

Q. No. .0018, that's not a percentage; right?

A. Oh, yes, you're right. I'm sorry. It's .18 percent. 03:18:32

Q. All right. Did you remember in school how you take that and you make it into a percentage?

A. Yes.

Q. So if you have .0018. That's when you divide 60,495 into 112, you get .0018; right? 03:18:54

A. Yes.

Q. And how do you convert that into a percent?

A. Multiply it times 100.

Q. And don't you move the decimal point over --

A. Correct. 03:19:07

Q. -- by two places? 03:19:07
A. Two spaces, yes.
Q. So in actuality, and this is exciting for me, to correct the math, the true math here with the equation Mr. North put up, would be 18 percent; correct? 03:19:17
A. No. .18.
THE COURT: Not so exciting.
BY MR. O'CONNOR:
Q. But just so we're clear, here's my point, .18 percent. The point is to get to what you want is you move the decimal 03:19:44
point over and that would be the accurate percentage; correct?
A. Yes. It's .18 percent, right.
Q. Right. Thanks. And I told you I was bad at math but apparently a little bit better than somebody in the courtroom.
All right. Now, you talked about the right way or a 03:19:59
better way to do a study to understand adverse events and you mentioned Binkert trial. Do you recall that?
A. Yes.
Q. May we have Exhibit 3781.
MS. REED ZAID: Mr. O'Connor, what's the exhibit 03:20:47
number?
MR. O'CONNOR: 3781. Scroll down a little bit.
BY MR. O'CONNOR:
Q. First of all, what is Binkert study, Dr. Hurst?
A. It was also called the EVEREST trial. It was a 03:21:29

Bard-sponsored research study to evaluate the safety and efficacy of retrieving the G2 filter. So it was not designed to study the safety and efficacy of the filter over a long-term of implantation in the patient but it was designed to see, hey, can we retrieve this thing? 03:21:33 03:21:59

Q. And during the course of that study, did -- and when was that study conducted?

A. From 2005 to 2006.

Q. Now, when were the results published?

A. 2009. 03:22:15

Q. 2009. Now, you understand that Sheri Booker's filter was implanted in 2007.

A. Yes.

Q. And the IFU that was applicable to her case we looked at earlier did not have any reference to any study. Is that fair? 03:22:29

A. I am not sure whether the data was published. We would have to look at the IFU.

Q. Let's look at the date of the Binkert study.

A. 2009 was when the study was published. They may have put the information in there prior to publishing it because it was their trial. 03:22:50

Q. Pardon me?

A. Because it was their trial, they may have put the information in there prior to publishing it.

Q. Okay. But the IFU you looked at didn't reference that 03:23:04

study, did it? 03:23:06

A. I'm looking at it right now. Sorry, it's really small type.

No, I do not see mention of that trial in the IFU.

Q. And if we may, Binkert study, is that an article that 03:23:44 you're familiar with?

A. Yes.

Q. Did that study talk about G2 failure rates?

A. The study describes the incidence of failures in that particular study, yes. 03:24:00

MR. O'CONNOR: Your Honor, for purposes of -- may I ask this witness to read from the results section?

Can you go to results, please, Greg.

THE WITNESS: I have it.

MR. O'CONNOR: I want to see it here. 03:24:19

BY MR. O'CONNOR:

Q. And do you see in results, Dr. Hurst, where it talked about cranial migration of the G2?

A. Yes. There were no cases of cranial migration.

Q. Caudal migration? 03:24:38

A. Caudal migration was observed in 12 percent of the cases, 10 out of the 85 patients that they evaluated.

Q. And during the course of this Binkert study, the retrievability study, were there other G2 complications that were found? 03:24:53

A. There was one filter fracture. There was a filter tilt in 15 patients so that would be 18 percent. There was leg penetration with 16 patients out of 61. They only had imaging on 61 to evaluate penetration but that was 26 percent of the patients. And then the recurrent pulmonary embolism rate or basically the occurrence of a PE that actually went through the filter was two percent. 03:24:55 03:25:16

Q. All right. So to summarize, Binkert study was specific to the G2 filter; correct?

A. Yes. 03:25:36

Q. And during the course of the study, I think you said that the purpose was to assess the technical success and safety for retrieval of the G2 filters?

A. Correct.

Q. But during the course there was a discovery by the people who were conducting the study that the G2 filter was failing? 03:25:47

A. They discovered multiple modes of failure, yes.

Q. And the failures were caudal migration 12 percent for the G2?

A. Yes, m'hum. 03:26:11

Q. Filter fracture was 1.2 percent?

A. Correct.

Q. Filter tilt was -- of more than 15 degrees was 18 percent?

A. Correct.

Q. And penetration of the leg was 26 percent? 03:26:25

A. Yes.
Q. And that was how many people participated in that study?
A. There were 100 total patients.
Q. And in terms of studies, what type of study was it?
A. It was a prospective trial. 03:26:39
Q. And before the G2 was released as a permanent filter, are you aware of any type of study, any such study that was done like that before the G2 was released as a permanent device?
A. On the G2?
Q. Yes. 03:26:58
A. No. This was the first study that was I think released on the G2.
Q. And it was published in 2009?
A. Yes.
Q. After Sheri Booker's filter? 03:27:05
A. Yes.
Q. Now, when we were looking at Bard's internal documents before during your direct -- correct?
A. Yes.
Q. -- and you saw that there were people in Bard that were 03:27:31 concerned about the failure of the Recovery to stay centered. Do you recall that?
A. Yes.
Q. You saw where the medical director was concerned about the G2 in comparison to the Simon Nitinol filter as it relates to 03:27:45

caudal migration. Do you recall that? 03:27:53
A. Yes.
Q. And you saw where the company acknowledged that it did not have a thorough study of caval dynamics before it released the G2. Did you see that? 03:28:10
A. Yes.
MR. NORTH: Objection, Your Honor. Cumulative and outside the scope of cross.
THE COURT: Overruled.
BY MR. O'CONNOR: 03:28:21
Q. And those documents are something that Bard did not share with the medical community, did they?
A. They did not.
Q. But as a physician with reasonable expectations, wouldn't you expect that a medical director of a company like Bard would want to be kept apprised of failures that the G2 was experiencing? 03:28:38
A. Yes.
Q. And so to that extent, when Bard gives these internal studies and we see them for the first time in court, those documents are telling you in the medical community and people here for the very first time what Bard actually knew about the filters; is that right? 03:28:57
A. Yes.
Q. And that information about the failures that Bard was 03:29:13

aware of was known to Bard before the G2 was ever released, wasn't it? 03:29:17

MR. NORTH: Objection, Your Honor. That's strictly barred I believe by the *Daubert* ruling.

THE COURT: Sustained. 03:29:30

BY MR. O'CONNOR:

Q. Well, Dr. Hurst, when we look at Bard's filters -- you're using the Denali today; correct?

A. Yes.

Q. And you were asked questions by Mr. North about Sheri Booker's doctors; right? 03:29:44

A. Yes.

Q. Now, Sheri Booker received a G2 filter that was cleared for permanent use. Is that true?

A. Yes. 03:29:59

Q. And I think you told -- the reasonable expectations of a permanent filter are what, absent any other information from the company, a permanent filter in terms of where it should remain?

A. It should remain in the inferior vena cava. 03:30:16

Q. And were there any warnings back in the time that Sheri Booker received her G2 permanent filter to doctors that they had to monitor the G2?

A. No.

Q. Were there any warnings to doctors like Sheri Booker's 03:30:36

doctors and doctors like yourself that it's not a matter of if, it's just a matter of when this filter is going to fail? 03:30:40

A. There were no warnings like that.

Q. Did Bard ever send out anything in 2007 or thereafter telling you doctors: Attention, we have a dangerous filter. Check every patient that received it. The G2 is not acting like a permanent filter. Did you receive anything like that? 03:30:57

A. We didn't receive anything like that. Specifically, though, they didn't recommend imaging and that was the big issue. I think if we had had some recommendations on follow-up of this device with imaging, which was actually recommended by the first physician who did the very first trial, on the Recovery device, after he did that trial he made a recommendation that these filters be followed with serial imaging, even just a plain preliminary, a radiograph x-ray of the abdomen probably would have been appropriate for these devices, but there was no recommendation for any sort of imaging follow-up. 03:31:18 03:31:43

There was a very weak recommendation for a clinical follow-up but no more than what had already been out there as the standard of care. 03:31:58

Q. Did Sheri Booker's doctors, like you, have any reason to know that the G2 permanent filter was going to caudally migrate, that it was going to tilt, that it was going to perforate, that it was going to break, that it was going to go 03:32:19

to her heart? 03:32:22

MR. NORTH: Your Honor, objection. 602. No foundation.

THE COURT: Sustained.

BY MR. O'CONNOR: 03:32:26

Q. Did Sheri Booker or you have any information from Bard to let you know that there was going to be a cascade of failures in the G2 filter?

A. There was no --

MR. NORTH: Objection. 03:32:36

THE COURT: Excuse me. there's an objection.

MR. NORTH: 602 again.

THE COURT: Sustained.

BY MR. O'CONNOR:

Q. Were there any warnings about cascade failures, Doctor? 03:32:42

A. No.

Q. And is that what was experienced once they were out there, the cascade of the G2 failures?

A. Yes.

Q. When you put in any filter now, have you changed your practice? 03:33:17

A. As I described previously, the current practice for patients who need temporary caval filtration is to place a retrievable device and then we do follow-up at somewhere between three to six weeks and determine whether the patient is 03:33:34

going to need the filter or not. And then if they do need the filter for a longer period of time, after a discussion with them, we may leave it in for another month or so. But if they are going to need a permanent filter, we'll take the retrievable filter out and put a permanent one in because they are more durable. 03:33:38 03:33:51

Q. After doctors were seeing the G2 failure after they had implanted those in patients, were patients basically leaving and not coming back because there were no warnings to return?

A. Correct. 03:34:12

Q. And was there any reason doctors like you would know, back in 2007, 2008, and even 2009, that if you were going to use a Bard filter, a G2 permanent, that you should have a program to follow up with those patients?

A. No. 03:34:34

Q. Is that something that physicians like you should have been able to reasonably expect from Bard if Bard was aware back here in Tempe, Arizona, that filters were failing just like we saw in a number of those internal documents here today?

A. Those recommendations would have been nice. 03:34:52

Q. Would they have saved some patients?

A. Perhaps.

Q. That's all I have.

THE COURT: All right. Thank you, Doctor. You can step down. 03:35:03

THE WITNESS: Thank you. 03:35:03

(Witness excused.)

THE COURT: All right. Your next witness, counsel?

If you had want to stand up, ladies and gentlemen, while we're waiting for the next witness, feel free. 03:35:18

MS. REED ZAID: Your Honor, the next witness will be testifying by a videotaped deposition. I take that back. We have a live witness.

MR. O'CONNOR: We have a live witness.

THE COURT: And who is that? 03:35:59

MR. O'CONNOR: Lora White.

THE COURT: Mr. O'Connor, who is that witness?

MR. O'CONNOR: I'm sorry, Your Honor?

THE COURT: Who is the witness?

MR. O'CONNOR: Lora White. 03:36:16

COURTROOM DEPUTY: Ma'am, if you'll please come forward. Raise your right hand.

(LORA WHITE, R.N., a witness herein, was duly sworn or affirmed.)

COURTROOM DEPUTY: Please come have a seat. 03:36:34

DIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Would you introduce yourself to the members of the jury?

A. Hi. I'm Lora White.

Q. And Ms. White, what do you do? 03:37:05

A. I'm a nurse, registered nurse. 03:37:07
Q. And in terms of why you're here, what is your role here today?
A. Well, I'm also a case manager and a life care planner so I prepare estimates of cost of future medical care for a particular injury. 03:37:21
Q. Would you explain to the jury what you did in this case?
A. So for this case, I read over the medical records that I had and I talked to Dr. Muehrcke and Dr. Hurst, they are two experts that are knowledgeable about what happened to Ms. Booker, and I asked them what their future medical care would look like for her. And when you do these things, you do probable or likely medical care and they gave me a list of things they wanted and I put -- I costed those out and put those in this report. 03:37:43 03:38:02
Q. And your report is Exhibit 2460 -- excuse me. 2463.
MR. O'CONNOR: Could you put that up, please, Greg.
Q. All right. Ms. White, you're an R.N. but you're also a consultant and you do life care plans; is that right?
A. Yes. I have. 03:38:30
Q. In this case, though, did you do a traditional life care plan?
A. No. For this -- a life care plan includes everything a person is going to need so medical equipment and things like that. This was just a cost projection. So it's kind of an 03:38:40

abbreviated life care plan. Kind of like a 1040-EZ so to speak. 03:38:42

Q. And tell us your qualifications to come here into this court and tell this jury about cost projections for medical care. 03:39:00

A. So I'm a nurse and I went to school to get the additional training necessary to do these and it's about a 40-hour class and then you take a test. So you have to prove that you can do it, that you know -- just like the case management certification. 03:39:16

Q. And to arrive at opinions in a case, I think you said you talk to medical doctors?

A. Yeah. I can make nursing recommendations based on a nursing diagnosis so I can say they are going to need home care, equipment, that kind of thing. For Ms. Booker, though, the care was medical care and so I'm just a nurse. I need to ask doctors what their recommendations are for that so that's what I did. 03:39:33

Q. And so how did you go about -- did you follow a methodology that is utilized by experts in your field? 03:39:48

A. Yes.

Q. Explain to the jury what did you to go out and put together a cost projection for Ms. Booker.

A. So once I got the recommendations from Dr. Muehrcke, I contacted the providers in her local area and just asked 03:40:00

them -- you have to code the things. You have to do something called a CPT code, you guys are probably familiar with. It's what doctors use to bill. And I just called the billing offices and then asked them what is your charge for this particular thing and they told me. 03:40:05 03:40:18

For her area, which is out of Georgia, it was pretty easy because they have a cost line that you can call. So -- and then I compared to it the national databases to make sure it was within the range of what would be considered normal so to speak. 03:40:34

Q. So when you talked to the doctors about Sheri Booker -- first of all, what type of information did you have about Ms. Booker and what was the condition you were looking at?

A. The Bard filter broke apart in her and so -- sorry, my glass was leaking -- and pieces went different places and one of the pieces landed in her inferior vena cava which is a major vascular -- I think it's an artery. I should know this, I'm a nurse. But it embedded in there and got into her aorta. So it's kind of dug in there so they couldn't get it out. Because part of it went also to her right ventricle I think it was, she has a risk of developing an arrhythmia so her heart might, according to Dr. Muehrcke, flip in and out of arrhythmia so they wanted to monitor that. And that's really all I put in was monitor. 03:40:57 03:41:16

Q. Did you actually go about and determine what monitor -- 03:41:34

how much monitoring Ms. Booker would require? 03:41:38
A. Yes. I put in what Dr. Muehrcke said, which is annual echocardiograms, a CT and follow-up visits with the doctor. Dr. Hurst also said to put in some anticoagulation for her, but she had a history of a DVT and a pulmonary embolism so it's 03:41:54
likely that she would have needed that anyway, so I did not put that in because she had it before.
Q. So did you attempt to address care and related cost to injuries that you learned she sustained because of the filter, Ms. Booker, that is? 03:42:12
A. That's correct.
Q. And did you go about and based upon your discussions with doctors, did you break down the type of care she would need?
A. Yes.
Q. And tell the members of the jury what you found item by 03:42:24
item, please.
A. It's on the next page. Can you -- of the report. It's physician evaluation and then a CT annually of the abdomen and pelvis to monitor where that fragment still is to make sure it's not moving around and then the echocardiogram. 03:42:43
Q. So let's just talk about did you determine whether -- did you arrive at costs for a physician evaluation of an initial physician?
A. Correct, I did.
Q. And what was the purpose for that? 03:43:00

A. So to establish care with a cardiologist that could follow her. 03:43:02

Q. And did you determine a cost that was reasonable?

A. Yes.

Q. And what was that cost? 03:43:12

A. $335.

Q. All right. Then did you look at types of treatments that Ms. Booker would have to receive on a regular basis?

A. Yes. Dr. Muehrcke -- do you want me to tell?

Q. Yes. Go ahead and explain to the jury, please. 03:43:26

A. Dr. Muehrcke said just the follow-up visits and the CT of the abdomen and pelvis and then the echocardiogram.

Q. And so how many follow-up visits did you cost out?

A. Two per year.

Q. And how did you determine the number of years that Ms. Booker will require those follow-up visits? 03:43:41

A. Well, when you do these plans, you usually do statistical life expectancy unless someone comes in and says it's likely that they are going to die, so that was not -- that information was not given to me. 03:43:57

So I don't calculate that part out. That's the next witness you're going to see.

Q. So did you determine what cost there would be for physician follow-up twice a year for the issues of arrhythmias?

A. Yes. 03:44:12

Q. And what did you find? 03:44:13
A. It's 540 for two visits so 270 times two which is the billed rate.
Q. And then was there any discussions with the doctors about imaging studies? 03:44:28
A. That's the CT, yes.
Q. And what did you determine there?
A. That she would need one per year and the cost would be $3,357. That is a CT with and without contrast.
Q. And is that on an annual basis? 03:44:42
A. Yes.
Q. And how much did you determine that would cost each year that Ms. Booker is alive?
A. 3357. That also includes the reading of the CT from the doctor because the doctor that reads it has to get paid, too, right? 03:44:57
Q. And then were there any types of tests that you were advised Ms. Booker would require?
A. The echocardiogram.
Q. And what is an echocardiogram? 03:45:08
A. They use an ultrasound to make an image of your heart so, you know, it's not an EKG where they slap leads on you. EMTs do that. You see it on the television but an echocardiogram, you have to do it under ultrasound. It gives the doctor a really good vision of what the structure of the heart is doing 03:45:26

and what is going on, especially with that valve. 03:45:29
Q. So to summarize what you found, you found that she needs to establish a one-time physician visit to establish care?
A. Correct.
Q. And that cost would be a one-time $335? 03:45:42
A. That's right.
Q. And then she needs to have physician follow-up for the arrhythmia and heart-related problems from the filter twice a year?
A. Correct. 03:45:53
Q. And that is a total of $4540 a yearly.
A. That's right.
Q. And then an annual CT of the abdomen and pelvis you said is an annual amount --
A. Yes. 03:46:03
Q. -- of $3,357?
A. That's right.
Q. And then the echocardiogram, again, she needs to do that annually?
A. Yes. 03:46:11
Q. And that is $1446?
A. That's right.
Q. And where did you go? How did you look to arrive at those numbers?
A. Like I said, I called the providers in the area. Gwinnett 03:46:20

has a cost line that you can call and they will tell you what it is, so it's really easy. But then I compared it to the databases I have. You have to subscribe -- I subscribe to these national databases and compare it to that to see if it's within -- what you would expect for that geographic region. You put in the ZIP code and the CPT code and it will tell you the average billed amount for that area. 03:46:25 03:46:38

Q. Now, you work with an economist?

A. I do.

Q. And who is that? 03:46:54

A. Matt Sims. I think he's on next.

Q. And what does Mr. Sims do?

A. He's an economist so he present -- he takes these numbers and does something with it to come up with that $242,023.

Q. Now, based upon what you told us today, the need for physician follow-ups twice a year at $540, the need for annual CT of the abdomen and pelvis on a yearly basis at $3357 and an annual echocardiogram each year at $1446, are those opinions that you've reached to a reasonable degree of life care planning probability? 03:47:08 03:47:36

A. Yes.

Q. And to get the total and present value and the number of years over a lifetime, I have to ask Mr. Sims about that?

A. That would be smart.

Q. All right. I don't have any other questions for you. 03:47:49

THE COURT: Cross-examination? 03:47:54

MR. CONDO: Thank you, Your Honor.

CROSS - EXAMINATION

BY MR. CONDO:

Q. My name is Jim Condo. You and I have never met I don't believe? 03:48:27

A. Not that I remember.

Q. Thank you. If I understand what you were asked to do, you were essentially provided with recommendations for probable future treatment which Ms. Booker may require according to Drs. Muehrcke and Dr. Hurst; correct? 03:48:40

A. That's correct.

Q. And then you took those probable or recommended future treatments and you essentially costed them or priced them based upon information where you reviewed primarily in the Gwinnett County, Georgia, metropolitan area? 03:49:02

A. That's right.

Q. And you relied on the opinions of Drs. Muehrcke and Dr. Hurst in forming the opinions of doing the costing that you've done in this matter; correct? 03:49:22

A. Yes, but remember I said that Dr. Hurst had recommended ongoing anticoagulation but I didn't put that in.

Q. Right. Because that was treatment that she was probably going to have to have anyway because of her preexisting medical condition; correct? 03:49:40

A. She had a history of a DVT and a pulmonary embolism. 03:49:41
Q. You know that Ms. Booker was never a patient of either Dr. Muehrcke or Dr. Hurst; correct?
A. That's correct.
Q. You know that they have never seen her clinically to do an examination or treat her in any fashion; correct? 03:49:56
A. That's correct. I don't know if they have seen her but I knew they weren't treating her.
Q. Now, your projections just cover the cost of life-long medical monitoring; correct? 03:50:12
A. That's right.
Q. They don't include any figures for future surgeries or anything of that sort; correct?
A. Right, because -- can I explain?
Q. Just answer the question yes or no. 03:50:25
A. Okay.
Q. They did not include --
A. That's right.
Q. Thank you.
And you did not adjust any of your projections 03:50:31 because I think you said on direct exam that no one said Ms. Booker was going to die?
A. Correct. Well, she's going to die but not before the statistical life expectancy.
Q. Fair enough. We're all going to get there one day but not 03:50:50

as a result of this. 03:50:53

All right.

A. Not that I have been told.

Q. In preparing your projections, you didn't speak with Ms. Booker's treating physicians, did you? 03:51:00

A. I did not.

Q. You didn't talk too Dr. Patel?

A. No.

Q. And you don't know whether they agree or disagree with the recommendations of Drs. Hurst and Dr. Muehrcke with respect to 03:51:12 recommended future course of treatment; correct?

A. Well, in the deposition of Dr. Patel, it appeared that he agreed with everything that Dr. Muehrcke and Dr. Hurst had said so that's kind of not true. But I didn't speak with them but I read their deposition -- or his. 03:51:31

Q. And is he the doctor -- you read his deposition is what you're saying?

A. Well, Dr. Patel. I don't know if it's a woman or a man.

Q. Okay. And although you and I haven't met before, you have worked with Mr. O'Connor and his law firm many times in the 03:51:52 past, haven't you?

A. Define "many." Several times, yes.

Q. Several times. Is that something we should ask Mr. Sims about how many times he's worked with Mr. O'Connor?

A. I don't know. You'll have to ask him. 03:52:09

Q. You do about 70 to 100 of these cost projections per year if I understand it? 03:52:11

A. Mostly life care plans.

Q. And about 90 percent of the income that you earn is resulting from litigation matters; correct? 03:52:23

A. That's correct.

Q. And for testifying here today, your hourly rate is $450.

A. Yes.

Q. Thank you. I have no further questions.

THE COURT: Any redirect? 03:52:36

MR. O'CONNOR: Yes, Your Honor.

REDIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Do you work for a lot of firms in Arizona?

A. All over the country. 03:52:52

Q. Do you know Snell and Wilmer?

A. Yes.

Q. That's where Mr. Condo is at. Do you do work for that firm?

A. Yes, I do. 03:53:00

Q. How much?

A. I don't know. Several times.

Q. But when you do work as you did here, you talked to doctors -- why did you choose Dr. Hurst and Dr. Muehrcke?

A. Because I knew that they were experts in this field. I 03:53:10

knew that they had reviewed everything and they -- they were qualified to tell me what she was going to need. If I called a primary care physician, they don't have that expertise necessarily so that's why. 03:53:12

Q. All right. And was it because you understood that they had access to the entire medical history? 03:53:24

A. Yes, they did.

Q. And was that important to you?

A. Well, yes. Yes. I want to get the right doctor with the right information, right, so that can speak knowledgeably. 03:53:35

Q. And do you feel that they gave you a good basis for the opinions of the costs that you've talked to this jury about today?

A. Yes. It's very conservative.

Q. And I'm going to talk to Mr. Sims in a moment. 03:53:48

A. Okay.

Q. Thank you.

MR. CONDO: That's all I have, Your Honor.

THE COURT: All right. Thank you.

(Witness excused.) 03:53:56

COURTROOM DEPUTY: Sir, if you'll come forward, please.

(JAMES MATTHEW SIMS, PH.D., a witness herein, was duly sworn or affirmed.)

COURTROOM DEPUTY: Could you please state your name 03:54:57

for the record. 03:54:58

THE WITNESS: James Matthew Sims.

DIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Would you introduce yourself to the jury, please. 03:55:26

A. My name is James Matthew Sims.

Q. And Mr. Sims, what do you do? What is your profession?

A. I call myself a vocational economist.

Q. Vocational economist. What does that mean? What do you do? 03:55:41

A. I perform vocational evaluations and I also perform economic evaluations so I do both, so I just call myself a vocational economist.

Q. Does that involve math?

A. Yes. 03:55:52

Q. Because there's at least two of us here that need help with that. Did you do calculations in this case?

A. I did.

Q. All right. Now, Mr. Sims, would you tell the jury what you were asked -- by the way, what type of training and 03:56:03 education do you have to qualify you to come in to talk to this jury today?

A. In short, I have two master's degrees, one is in counseling and that goes into the vocational rehabilitation area. I didn't do any of that in this case. My other is I 03:56:19

have a master's of science in economics from Arizona State University and I have been doing forensic economic evaluations, about 120 a year, since March of 2000. 03:56:23

Q. Now, you work with Lora White?

A. Yes. 03:56:40

Q. How does that work between the two of you? Ms. White just came in and told us how she projected costs for certain care that Ms. Booker is going to require for the rest of her life. Are you aware of that?

A. Yes. 03:56:53

Q. And then what do you do with that information?

A. Well, I perform what's called a present value calculation. Because her life expectancy is going out another 34 years into the future and there's going to be a lot of inflation and so the prices that exist today, they are going to be increasing over time, so I put an inflationary calculation in there. 03:57:11

And then I perform one more calculation essentially. I discount it to present-day value. In other words, if someone needs $105 next year to pay for something and if you have a bunch of money and you can invest it and earn interest at five percent interest, you only need $100 today. So I take that 105, I discount to it 100, the amount of money that you need today. So I essentially factor out a little bit of interest. 03:57:32

Q. Mr. Sims, in this case, what exactly did you do for the cost projection that Lora White looked into, researched and 03:57:56

arrived at opinions on? 03:58:01
A. I projected them out all the way through Booker's statistical life expectancy. I applied the inflationary increases and then I discounted those dollar amounts to their present day value. 03:58:17
Q. Did you use the type of methodology to arrive at your conclusions that are used by experts in your field?
A. Yes.
Q. Did you put together your calculations on a document, on a piece of paper. 03:58:31
A. Yes, I did.
Q. Is that the future medical care cost economic estimate?
A. Yes.
MR. O'CONNOR: Can we see Exhibit 4388?
BY MR. O'CONNOR: 03:58:49
Q. Will this exhibit help explain your opinions and how you came to a present day value for Ms. Booker to the jury?
A. If you have it up there. I don't have anything on my screen.
COURTROOM DEPUTY: Oh, I'm sorry. There we go. 03:59:00
BY MR. O'CONNOR:
Q. Can you identify what we're looking at as Exhibit 4388?
A. Yes. This is the economic table I created.
Q. And to get through this relatively quickly, can this help explain your calculations and how you arrived at opinions 03:59:17

regarding the amount that the cost projection will cost? 03:59:20
A. Yes. The very left column --
Q. Hang on.
MR. O'CONNOR: Your Honor, may I publish this to the jury just for purposes of assisting Mr. Sims in explaining his work. 03:59:30
THE COURT: Any objection?
MR. CONDO: No objection if it's a demonstrative exhibit.
THE COURT: All right. 03:59:39
You may show it as a demonstrative.
BY MR. O'CONNOR:
Q. What are we looking at?
A. The very left column is the calendar year and then the next column over is her age. The third column over, 03:59:48
professional care services, those are pretty much doctors' visits. So those are the dollar amounts that Lora came up with and I'm applying them every year into the future.
The next column over that says growth rate factor, that number going down gets a little bit bigger and bigger and 04:00:08
bigger and so that's the inflation that I'm talking about. So I'm increasing the $540 a year by an inflationary factor. The next group over, those are I believe -- I think she had CT scans and echocardiograms. Those are done at the facilities and so those are $4803 a year every year into the future. And 04:00:31

the next rate over is the inflationary growth rate factor for those costs. The next column over, medical care commodities, that wasn't used in this case and neither was the next one, growth rate. That wasn't used in this case. 04:00:38

The second-to-the-last column that says discount rate per year, that's the discounting based on interest rates. And I only used the safest and most secure interest rates from U.S. Treasury securities so I'm not putting anyone at risk of losing out on any of the money that they need. 04:00:53

The final column over is the present value amount year by year and into the future. 04:01:13

Q. So now, Ms. White gave us four categories. She said there's going to be a one-time visit to establish care with a physician at Gwinnett Medical Group at $335. Where do we see that? 04:01:32

A. That's going to be in the third column over.

Q. I think you can touch the screen and maybe put an asterisk on there.

A. The third column over, the very first dollar amount, there is the dollar amount for the initial visit. One time only, $335. The $540 amount that you see in the column below, those are for two visits a year; but since I began 2017 halfway through the year, I only did one visit. So there's one initial visit and that $605 plus one follow-up visit for the calendar year. 04:01:52 04:02:19

Q. All right. And then there was an annual CT of the abdomen and pelvis. 04:02:19

A. Those would be in the $4803.

Q. The amount Ms. White gave us was 3357 but she also projected the need for an annual echocardiogram at $1446. Did you include that? 04:02:35

A. Yes.

Q. Now, how long did you project these costs out for?

A. Through her statistical life expectancy.

Q. And how do you go about determining a statistical life expectancy? 04:02:52

A. Pretty much every economist relies on the National Vital Statistics Report on life expectancies.

Q. Is that the type of information that is reasonably relied upon by experts in your field? 04:03:12

A. Yes, all the time.

Q. And so let's go to the next page. So how many pages is your table?

A. That's the end of it there.

Q. So if you would, explain to the members of the jury, what was Ms. Booker's life expectancy? 04:03:28

A. It extends out to the year 2051.97.

Q. All right. And based upon the life care -- life-long cardiac monitoring plan that Lora White gave you and those individual costs, were you able to arrive at the present value 04:03:52

of the cost for that care over her lifetime? 04:03:57
A. Yes.
Q. And what did you determine?
A. It was $242,023.
Q. And is that a calculation and opinion that you hold to a reasonable degree of economist probability? 04:04:11
A. Yes.
Q. And you did that by applying the factors that you told us about; is that correct?
A. That's correct. 04:04:22
Q. And why do you put it in present value?
A. Because it's representative of the dollar amount that is needed today. If you invest it, you'll be a able to cover all of the medical costs that my partner, Lora White, had in her plan. 04:04:42
Q. So what you -- did you determine an amount that will provide for Ms. Booker to receive the type of care described by Lora White over her lifetime?
A. Yes.
Q. And that amount is $242,023? 04:04:52
A. Correct.
Q. Thank you. That's all I have.
THE COURT: Cross-examination?

CROSS - EXAMINATION

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BY MR. CONDO: 04:05:09

Q. Mr. Sims, I think I have perhaps just two or three questions for you. My name is Jim Condo. We've never met before, have we, sir?

A. No. 04:05:17

Q. Now, you projected Ms. Booker's life expectancy until age 82; correct?

A. Yes.

Q. You did not make any adjustments in her life expectancy based upon any of her medical conditions; correct? 04:05:25

A. Correct. I don't really know much about the medical stuff here.

Q. Okay. So there is no adjustment in your projections for a shortened life expectancy as a result of anything that may have occurred with respect to the implant or removal of the filter 04:05:42 she had; correct?

A. Correct.

Q. Thank you.

MR. CONDO: I have no further questions.

THE COURT: All right. Thank you. 04:05:51

Well, any redirect?

MR. O'CONNOR: Just really quick, Your Honor. Thank you.

REDIRECT EXAMINATION 04:05:55

BY MR. O'CONNOR:

Q. And the projections and the life care expectancy, is that based upon methodology used by experts in your field?

A. Yes. 04:06:04

Q. Thank you.

MR. CONDO: That's all I have.

THE COURT: All right. Thank you.

Sir, you can step down.

THE WITNESS: Thank you. 04:06:08

(Witness excused.)

MS. REED ZAID: The next witness, Your Honor, is Dr. Marcus D'Ayala. He will be appearing by videotape, and we have the agreed-upon summary of his background, if I may read it to jury. 04:06:41

THE COURT: You may.

MS. REED ZAID: Dr. Marcus D'Ayala is chief of vascular surgery at New York Methodist Hospital in New York City. He's an associate professor of clinical surgery at Weill Medical College of Cornell University. He graduated from the 04:06:51 University of Wisconsin Medical School in 1992, completed a vascular fellowship in 1998, and earned his board certification in vascular surgery in 2000.

On June 21, 2007, Dr. D'Ayala implanted a G2 IVC filter in Ms. Sheri Booker. Your Honor, we also have the 04:07:13

exhibits that will be appearing in the video that I would like to read off and move into evidence. 04:07:17

Trial Exhibit 2244, which is D'Ayala Exhibit Number 2 at his deposition; Trial Exhibit 2057 is Exhibit 3 to his deposition; trial Exhibit 994, which is Exhibit Number 4 to his deposition; Trial Exhibit 2321, which is Exhibit Number 8 to his deposition; and Trial Exhibit 1001 which is Exhibit 13 to his deposition. 04:07:36

THE COURT: And are you moving those into evidence?

MS. REED ZAID: Yes, sir. 04:07:58

THE COURT: Any objection?

MS. HELM: No, Your Honor.

THE COURT: All right. Those exhibits will admitted. And you may play the deposition.

(Exhibit Numbers 2244, 2057, 994, 2321, 1001 were admitted into evidence.) 04:08:04

MS. REED ZAID: Thank you.

(Whereupon the deposition of Dr. D'Ayala was played.)

THE COURT: All right. Counsel. Let's stop the video there. 04:19:47

All right. We are at 4:20, ladies and gentlemen. We will plan to begin tomorrow morning at nine and we will excuse the jury at this time.

(Jury departs at 4:20.)

THE COURT: Please be seated. 04:20:22

All right. Counsel, without any adjustment for the portion of Hudnall that was played this morning or for Dr. D'Ayala's deposition, plaintiff has used 15 hours and 14 minutes; defense has used four hours and 50 minutes, five zero. 04:20:41

Are we still planning tomorrow morning to talk about the FDA letter? 04:21:02

MS. REED ZAID: Yes, Your Honor.

THE COURT: Okay. So I'll be ready for that.

MS. HELM: Your Honor, I can give you the agreed-upon adjustments for the Hudnall and Cohen depositions. Hudnall was finished this morning and Cohen was played this morning. 04:21:10

THE COURT: Okay.

MS. HELM: It's a total of five minutes that goes to the defendants.

THE COURT: Okay. So that would mean defendants have used four hours and 55 minutes and plaintiffs have used 15 hours and nine minutes. 04:21:24

All right. Any other matters we need to take up before we break?

Okay. We'll see you at 8:30. 04:21:42

(Whereupon, these proceedings recessed at 4:21 p.m.)

* * * * *

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 20th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP